

REMARKS-General

By the above amendment, Applicant has amended the title to emphasize the novelty and better define the invention. The original patent title : ULTRA-HIGH FIBER SUPPLEMENT AND METHOD OF WEIGHT REDUCTION has been changed to ULTRA-HIGH FIBER SUPPLEMENT AND METHOD OF WEIGHT AND CARDIOVASCULAR RISK REDUCTION.

The Improper Use Of Trademarks In The Specification Has Been Corrected.

Trademarks mentioned in application are capitalized. Applicant has been respectful of these trademarks and mentions them for the purpose of showing how applicant's invention is novel.

The embedded hyperlink has been removed.

Specification has been changed to correct these technical rejections.

Explanation of Claims

Claims 1-23 were canceled and new claims 24-64 are submitted. Claims 24-64 were rewritten to more particularly define the invention in a patentable manner over the cited prior art.

Applicant has been careful not to add new matter, and has provided direction to examiner by listing page numbers in original application to verify that information added was in original application.

Claim1 was canceled and rewritten as new claim 24 and now shows the nutritional supplement is orally administered to mammals and that the supplement must contain at least 7 grams of fiber per serving. Applicant has taken examiner's advice and removed the indefinite term "ultra-high" and replaced it with a numerical value. Applicant also removed the term "namely" as examiner suggested. Applicant submits that "per serving" is a proper term to use in a patent as the government defines food labeling requirements such as low-fat, low-calorie, fat-free, etc. based on a "per serving" basis. No new matter has been added, original application has numerous references to the minimum of 7 grams. See original application under detailed description of basic beverage p 16. The fact that applicant's invention has novel structure and allows delivery

of more fiber per serving than other prior art is important as it changes the focus of how it works and provides new and unexpected results.

Claim 2 was rewritten as claim 25. The word “contains” was changed to “comprises” to more clearly show that the nutritional supplement can have additional fibers as detailed in the specification.

Claim 3 was rewritten as claim 27. Examiner had objected to claim 3 reciting a group within a group, or overlapping groups. Claim 27 now refers to fiber in terms that are not overlapping soluble, partially soluble, and insoluble. This is not new matter and solubility is discussed in original application (Original p. 17.)

Claim 4 was rewritten as claim 28 that more clearly describes the novel physical structure (based on claim 24, now including at least 7 grams per serving) and shows more clearly that the nutritional supplement can be made into a **zero calorie** or calorie containing drink depending on what liquid is added. This is not new matter and is discussed throughout the original application.

Claim 5 is rewritten as claim 30. The term flavorant was removed as applicant could not find it in a dictionary, and flavorant was replaced by “substances that provide flavor.”

Claim 6 is rewritten as claim 31 and shows correction of the nutritional supplement according to claim 24.

Claim 7 is rewritten as claim 32 and shows correction of the nutritional supplement according to claim 24.

Claim 8 is rewritten as claim 33 and more clearly defines the tea and its components that can be added to the nutritional supplement. Claim 33 now shows that “at least one tea” and includes the

group of tea leaves, tea flavonoids, tea catechins and tea polyphenols. This is not new matter and is discussed on p. 21 of original application.

Claim 9 is rewritten as claim 34 and seeks to provide clarity over claim 9: The terms herbs, and botanicals have been replaced with “plant derived compounds” and the term “synthetic orally absorbable non toxic compounds” has been added to lessen the number of claims. Previously claim 12 had a number of additional ingredients that could be added and claim 12 has been eliminated. This is not new matter as applicant discusses “can be from any source safe for human consumption including natural, synthetic and any combination” (p. 20 original application and plant and synthetic compounds are discussed throughout original application. (Original application. p. 23 further explains “one or more substances safe for human consumption can be added to aid weight loss. These include natural, synthetic, or any combination of such substances...”)

Claim 10 is rewritten as claim 35 and shows correction of the nutritional supplement according to claim 24.

Claim 11 is rewritten to new claims 26 and 29 to provide more clarity. Claim 26 shows that the nutritional supplement can be made into a liquid, semisolid, or solid. Claim 29 shows that at least one additional ingredient must be added to create a solid or semisolid food product and further defines these as puddings, snack bars, wafers, and dog bones. This is not new matter as it was discussed in original application on page 53. Applicant submits that original application shows beverage and non-beverage alternatives to the supplement. While detail is provided for beverages, puddings, and snack bars, applicant describes on p. 53 of original application how semi-solid and solids can be made. Applicant considers the use of wafers and dog bones to be a solid comestible and therefore not new matter .

Claim 12 has been eliminated as claim 9 and 12 have been combined to make new claim 34.

Claim 13 has been rewritten as new claim 37 and now better shows a method of using the nutritional supplement to provide at least one health benefit to a mammal. The method includes the novel physical structure and the limitations that it is orally administered to a mammal at least one time daily. The list of benefits was expanded to more clearly show the definite benefits described in applicant's original application. All benefits listed are taught in the original application.

Claim 14 has been rewritten as new claims 38 and 39 and more clearly shows the method the supplement can be made into a beverage, a zero calorie beverage, and a variety of solid and semisolid food products. The method of 39 is made more definite as the edible food product must now be accompanied by an edible liquid that further hydrates the fiber. (This is not new matter and is discussed throughout original application and also on p. 54-56)

Claim 15 has been rewritten as claim 41 and more clearly defines the ingredients that can be added as detailed in the original application. Instead of listing the individual ingredients that can induce weight loss as listed in the specification the term "orally consumed substances that induce weight loss" has been used. This is not new matter, original application p. 23 further explains "one or more substances safe for human consumption can be added to aid weight loss. These include natural, synthetic, or any combination of such substances..." Also applicant directs examiner to original application p. 51 "The stimulants, thermogenics, and lipogenesis inhibitors that can be used are all synthetic and natural forms."

Independent method Claim 16 has been rewritten as new independent method claims 42 and 45 to further add clarity to the method of serving at least 7 grams of fiber to a mammal. Claim 42 details the method including adding the step of admixing an edible liquid, and shows that a zero calorie or calorie containing beverage could be made. Claim 45 better shows the method of making a semisolid or solid and the necessity of adding at least one ingredient to make the edible food product. The edible food products are better defined. Claim 45 also includes the step

accompanying the semisolid or solid with an edible liquid to further hydrate the consumed fiber. No new matter has been added.

Dependent claim 17 has been rewritten as new dependent claims 44 and 47. The method is better described as showing the need to further admix at least one ingredient. In search of brevity, several individual ingredients were replaced by more general terms. (Several plant compounds were removed and replaced with the term “plant derived compounds”, several ingredients that promote weight loss were replaced with the term “orally consumed substances that induce weight loss”). No new matter has been added, original application. p. 23 further explains “one or more substances safe for human consumption can be added to aid weight loss. These include natural, synthetic, or any combination of such substances...” Also applicant directs examiner to original application. p. 51 “The stimulants, thermogenics, and lipogenesis inhibitors that can be used are all synthetic and natural forms.”

Independent claim 18 has been rewritten as new independent claim 53 now better defining the method of reducing cardiovascular risk by showing improvement in at least one risk factor, serving the supplement to a mammal, administering at least once daily, and including the minimum of 7 grams per serving. No new matter has been added.

Dependent claim 19 has been rewritten as new dependent claim 55 better showing the method by indicating at least one ingredient is further included. Applicant has attempted greater clarity by removing words such as “botanicals and herbs” and replacing them with the term “plant derived compounds”. To better show what is taught in specification in making the supplement, additional ingredients are listed. For the sake of brevity, rather than listing individually some items that are known to improve cholesterol, lipoproteins, C-reactive proteins, and homocysteine, the term “orally consumed substances that improve cholesterol, lipoproteins, triglycerides, high sensitivity C-reactive protein, and homocysteine” has been added. This is not new matter. (original application p. 20 and last paragraph on p. 52, also throughout application).

Dependent claim 20 has been rewritten as new dependent claims 56 & 57 to better define the method. Claim 56 shows that by adding at least one edible liquid a beverage can be created and specifically identifies the beverage can be zero calorie or calorie containing. Claim 57 shows that at least one additional ingredient must be admixed to make a semisolid or solid food product. Claim 57 also shows the additional necessary step of consuming a liquid with the food product so as to further hydrate the fiber. No new matter has been added.

Independent claim 21 has been rewritten as new independent claim 58 and more clearly shows the method. Claim 58 shows that the supplement must be orally administered to a mammal and that the novel physical structure including a minimum of 7 grams of fiber per serving is necessary. No new matter has been added.

Dependent claim 22 has been rewritten as dependent claim 60, better defining the method and the ingredients taught. Claim 60 shows that at least one ingredient must be admixed to the supplement. To increase clarity the terms "botanical, herbs" have been replaced by plant derived compounds. Rather than listing the several individual ingredients taught to detoxify in the specification the term "orally consumed detoxifying substances" has been used. This is not new matter, see original application p. 20 including "Several antioxidants also have been scientifically proven to help detoxify and remove dangerous free radicals and toxins. These antioxidants can be from any source safe for human consumption including natural, synthetic, or any combination."

Dependent Claim 23 has been rewritten as new dependent claims 61 and 62 to better define the method. Claim 61 shows that by adding at least one edible liquid a beverage can be created and specifically identifies the beverage can be zero calorie or calorie containing. Claim 62 shows that at least one additional ingredient must be admixed to make a semisolid or solid food product. Claim 62 also shows the additional necessary step of consuming a liquid with the food product so as to further hydrate the fiber. This is not new matter.

Dependent claim 36 shows the ingredients that are added to the supplement of claim 24 in the preferred alternate embodiment 1A listed in the original application p 24.

Dependent claim 40 shows that at least one edible fiber can be added to the method claim of claim 37. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Dependent claim 43 shows that at least one edible fiber can be added to the method claim of claim 42. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Dependent new claim 46 shows that at least one edible fiber can be added to the method claim of claim 45. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Independent new claim 48 shows the method of how a mammal can use the supplement to lose weight. The supplement must contain at least 7 grams of fiber and must be consumed at least once daily by the mammal. No new matter has been added. The original application has multiple descriptions on how applicant's supplement can be used for weight loss.

Dependent new claim 49 further includes a method whereby a zero calorie or calorie containing beverage can be made. No new matter has been added.

Dependent new claim 50 further shows the method of admixing at least one ingredient to create a solid or semisolid food product and the additional step of accompanying the food product with

the consumption of a liquid to further hydrate the fiber. (This is not new matter and is discussed throughout original application and also on p. 54-56)

Dependent new claim 51 shows that at least one edible fiber can be added to the method claim of claim 48. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Dependent claim 52 provides the additional method step of adding at least one ingredient that is taught in the specification. Instead of listing the numerous weight loss inducing substances, applicant has replaced these numerous ingredients with the term “orally consumed substances that induce weight loss”. No new matter has been added, original application. p. 23 further explains “one or more substances safe for human consumption can be added to aid weight loss. These include natural, synthetic, or any combination of such substances...” Also applicant directs examiner to original application. p. 51 “The stimulants, thermogenics, and lipogenesis inhibitors that can be used are all synthetic and natural forms.”

Dependent new claim 54 shows that at least one edible fiber can be added to the method claim of claim 53. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Dependent new claim 59 shows that at least one edible fiber can be added to the method claim of claim 58. The fibers have been grouped based on whether they are insoluble or not to avoid the overlapping groups the examiner objected to in original claim 3. No new matter has been added.

Independent new claim 63 shows a method of reducing cardiovascular risk in mammals through ingesting an effective amount of fiber to lower the high sensitivity C-reactive protein levels.

This is not new information; it is discussed in original application p. 14, 16, and 36.

Independent new claim 64 is a means claim showing structure and function. Applicant’s novel structure including a minimum of 7 grams of fiber per serving is listed along with a means for

providing at least 7 grams of fiber to a mammal in a beverage that does not immediately gel. This is not new matter and clearly shows the novel structure and the function (preventing gelling with high dose fiber). The application has numerous references to these structures and functions.

Applicant thanks examiner for reviewing the email and then telling him application should pass if focused on the aspect of greater than 7 grams of fiber per serving and/or on the beverage aspect. Applicant especially is grateful to examiners for phone assistance. Applicant very much appreciates time and advice given by examiners, and appreciates that examiners stated they would work with applicant after receiving the amendment to achieve success at obtaining a patent.

Applicant provided an email to examiner after reviewing the office action. That email showed the physical structure of Leitz, and Gori, and how applicant's novel structure had numerous differences over Leitz, Gori, and the combination of the two. Applicant also pointed out how applicant's structure was unobvious over both.

THE CLAIM OBJECTIONS HAVE BEEN OBVIATED

Examiner objected to claims 14 and 15 under 37 CFR 1.75 (c) for having been written in improper dependent form for failure to limit the subject matter of independent claim 13. Claims 14 and 15 failed to provide limitations to a method of administering a composition.

Independent claim 13 has been rewritten as claim 37 and claims 14 and 15 have been rewritten as dependent method claims 38 and 39 with limitations to a method of administering a composition.

THE TECHNICAL REJECTIONS OF THE CLAIMS HAVE BEEN OBVIATED

All Claims have been rewritten to define the invention more particularly and distinctly so as to overcome the technical rejections and define the invention patentable over the prior art.

THE CLAIM OBJECTIONS UNDER 35 USC §112 HAVE BEEN OBVIATED

Applicant requests reconsideration and withdrawal of the claim objections.

Claims 1-15 and 18-23 were rejected as being indefinite due to the use of the term “ultra-high” in describing the fiber supplement. These claims were rewritten as new claims 24-41 and 48-62. Ultra-high has been removed from all claims and instead the term “at least 7 grams per serving” has been added.

Claim 1 was rendered indefinite due to the use of the word “namely”. This claim was rewritten as claim 24 and “namely” has been substituted by the words “which are”.

Claim 1 and 18 were rendered indefinite due to the use of the word “ultra-high”. These claims were rewritten as claim 24 and 53 “ultra-high” has been replaced by the term 7 grams or greater per oral unit dose .

Claims 13 and 21 were rendered indefinite due to the use of the word “ultra-fiber”. These claims were rewritten as claims 37 and 53. The word “ultra-fiber” has been replaced by the term at least 7 grams of fiber per serving.

Claim 13 was rejected due to the use of the word “said” in referring to the nutritional supplement. The word “said” has been removed. New claim 37 shows novel structure, benefits and function.

Claims 3, 19, and 22 were rejected as being indefinite for reciting a group within a group or overlapping groups. These claims were rewritten as claims 27, 55, and 60 so as to provide clearer distinction and have non-overlapping groups. Claim 12 was rejected as being indefinite for reciting a group within a group or overlapping groups. Claim 9 and 12 were combined to rewrite new claim 34 which applicant believes does not offer a group within a group.

Claims 19,20,22,23 were rejected for reciting the limitation “ the composition according to claim X...” when they were dependent claims on a method claim. These claims have been rewritten and replaced by claims 55, 56 & 57, 59, 61 & 62 and correctly state “The method according to Claim X...”

Claims 13-15 were rejected for being incomplete for omitting essential steps regarding the administering of the nutritional supplement and the fact that no host was provided. Claims 14 and 15 were dependent claims of independent Claim 13 and rendered indefinite due to Claim 13 being indefinite. These claims were rewritten as claims 37, 38 & 39, and 41, to include the host “a mammal” and to provide the step of orally administering at least 7 grams of fiber per serving to mammal. The dependent claims (38,39,41) all show an additional step or method of admixing an additional ingredient. New dependent claim 40 also shows the additional step of admixing at least one edible fiber to the method of claim 37.

Thus the present specification clearly and completely teaches how to make and use the invention in general.

Accordingly applicant submits that the specification does comply with § 112 and therefore requests withdrawal of all rejections.

**THE REJECTION OF CLAIMS 1,3,5,6, 10-12, 18 AND 20 UNDER SEC. 102
(b) IS OVERCOME.**

THE CLAIM OBJECTIONS UNDER 35 USC§102 ON LEITZ HAVE BEEN OBVIATED

Claims 1,3,5,6, 10-12, and 18 and 20 were rejected as being anticipated by Leitz (US Patent 4,877,627) under 35 USC §102

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art. Claim 24 now shows that the nutritional supplement is for mammals, and that it contains at least 7 grams of fiber per serving. Applicant respectfully requests reconsideration and allowance of these claims for the following reasons.

APPLICANT'S INVENTION

Applicant's invention is an ultra-high fiber (**at least 7 grams per serving**) supplement that is orally administered one or more times daily and **comprises a mixture of guar, oat, and psyllium fibers plus at least one flavoring agent**. Applicant's novel physical structure including specific fibers with specific physical characteristics allows for applicant's supplement to be delivered in a beverage, semisolid, or solid form. The beverage is novel in that a **minimum of 7 grams of fiber per serving** can be administered **in liquid form without immediately gelling**. No other fiber supplement provides a minimum of 7 grams of fiber that can be delivered safely in one serving. And no other fiber supplement exists that can provide a minimum of 7 grams of fiber per serving in liquid form without immediately gelling. A further novelty of applicant's beverage is that it can administer a minimum of 7 grams of fiber in a beverage that contains **zero calories**.

Applicant's invention provides many unique health benefits including dramatic weight loss, and reduction in cardiovascular disease. Applicant's invention also reduces the risk of acquiring or improves certain cancers, heart disease, glucose intolerance, diabetes,

metabolic syndrome, hypertension, osteoporosis, constipation, diverticulosis, hemorrhoids, irritable bowel, homocysteinemia, dyslipidemia, hypertriglyceridemia, and high sensitivity C-reactive protein (cardiac inflammation). Applicant's invention can be used to help prevent absorption and speed elimination of ingested toxins. Due to applicant's novel structure the nutritional supplement of claim 24 can be admixed with water to create a beverage that does not immediately gel. **Applicant's invention can be mixed with water or other zero calorie edible liquids to make a zero calorie ultra-high fiber (at least 7 grams per serving) beverage that does not immediately gel.** Applicant's supplement can also have at least one additional ingredient added to make a semisolid or solid comestible. Applicant's invention delivers ultra-high fiber (at least 7 grams per serving) in an easy and convenient manner without significant side effects. Applicant's invention delivers this ultra-high fiber (at least 7 grams per serving) without the need to replace minerals and nutrients that high fiber is known to sequester or block the absorption of.

Leitz

Leitz (US Patent 4,877,627)

Leitz's invention is a **balanced fiber composition that serves as an adjunct to the diet.** Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the **basic food group model** and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing **30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non-vegetable, and non-cereal group.** (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that **all of these fibers are needed** as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) He further pushes the variety of fibers "since **each basic fiber classification is represented by three fibers,** this variety of fiber

sources allows the unique fiber composition of the present invention to comprise an excellent adjunct to a diet.” Column 4 lines 33-37) . Leitz teaches that acerola, carrot, and lemon pulp powder are necessary for the fruit and vegetable group. Leitz teaches that corn, oat, and barley bran are necessary for the cereal group. Leitz teaches that soybean bran, guar gum, and psyllium seed husk is necessary for the non-fruit/vegetable/cereal group. Leitz teaches that **all** of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **It is important to note that all these fibers are required as Leitz is teaching a balanced fiber composition that delivers health benefits at a modest level of intake.** (column1 lines 65-68).

Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber. (Column 1 lines 59-68, and column 4 lines 42-44) Leitz further teaches a unit-of-use form [serving] of which he prefers a tablet, or bulk form. Leitz teaches his serving can contain from 0.5-5 grams of fiber, but **prefers 1-3 grams** and if in bulk powder form for a **beverage only 2 grams** is recommended. (column 5 lines 41-65). Leitz teaches that his composition typically **contains non-toxic inert carriers** to aid with oral administration. (column 4 lines 45-51). Finally, Leitz states that it is generally accepted that soluble fiber is associated with a reduction in LDL and serum cholesterol. (column 1 lines 39-55) Leitz does not in any way show that his composition reduces cholesterol, nor does he provide any method of cholesterol lowering.

In summary Leitz is a balanced fiber composition of **modest fiber intake requiring 9 different fibers** specially selected to provide desired nutritional benefits. (All 9 are required as evidenced by the individual range of each fiber of at least 1% noted in Table 1 [column 3]. Very **specific ratios** of three different fiber groups are required. Modest fiber per serving is essential to the composition as **Leitz teaches that large amounts of fiber are dangerous** and he wishes to provide a composition that is not dangerous. The composition is typically accompanied by an **inert non-toxic carrier**. The serving size can be 5 grams but is **preferred to be 1-3 grams per serving** unless the bulk powder is used in a beverage as Leitz teaches this should be only 2

grams. Applicant submits that Leitz “about 0-5 grams” should not be interpreted to mean more than 5 grams as he teaches he prefers 1-3 grams and if in a beverage he recommends only 2 grams. Since all Leitz recommendations are for much less than 5 grams, and he stresses the importance of a modest dose of fiber, it is not logical to assume he meant more than 5 grams. Furthermore, if he intended his composition to contain more than 5 grams per serving he would have said “about 6 grams....about 7 grams, etc.)

APPLICANT'S INVENTION HAS GENERAL DIFFERENCES OVER LEITZ

Applicant's present invention is totally different in structure and operation from Leitz. Applicant provides **at least 7 grams of fiber per serving**. Applicant provides a way to deliver ultra-high fiber (7 grams or greater per serving) to a mammal safely and without the need for nutrient and mineral replacement. Applicant can achieve this ultra-high fiber (7 grams or greater per serving) nutritional supplement with **as few as 3 fibers and without any fibers from the fruit or vegetable group**. Another difference is that applicant delivers **7 grams or greater of fiber in beverage form without immediate gelling**. Applicant provides a method for a mammal to have dramatic weight reduction and dramatic risk reduction in cardiovascular disease. Applicant has no interest in balanced fibers, balanced composition, the basic food groups, modest levels of fiber, or inert non-toxic carriers. Applicant is only concerned with delivering ultra-high fiber (7 grams or greater per serving) in a safe and easy to tolerate manner one or more times daily to optimize health and prevent or aid in treatment of a great variety of diseases.

Leitz, on the other hand, teaches to make a **balanced** fiber composition which requires fibers from 3 specific groups (fruit and vegetable, cereal, and other non-fruit, non-vegetable, and non-cereal group), with specific percentages of each group, with specific members of each group. **Leitz specifically requires 9 fibers which are acerola, lemon and carrot pulp, corn, oat, and barley bran and soybean bran, guar gum, and psyllium seed husk**. All are necessary to

make his balance fiber composition that is modeled after the basic food groups. **Applicant's invention differs in the number of fibers required, the types of fiber required, and the ratios of the fibers. These are all dramatic differences.**

Another critical difference is in the number of grams per serving. Leitz teaches that high levels of fiber are dangerous and he seeks to provide fiber benefits at a modest dose. Importantly Leitz teaches a **MAXIMUM of 5 grams** (0.5-5 grams per unit of administration [serving]) because all his preferences are for less than 5 grams. Leitz **prefers 1-3 grams** per serving. Leitz teaches the beverage should have approximately **2 grams of fiber** (column 5 lines 42-44). Applicant submits that Leitz "about 0-5 grams" should not be interpreted to mean more than 5 grams as he teaches he prefers 1-3 grams and if in a beverage he recommends only 2 grams. Since all Leitz recommendations are for much less than 5 grams, and he stresses the importance of a modest dose of fiber, it is not logical to assume he meant more than 5 grams. Furthermore, if he intended his composition to contain more than 5 grams per serving he would have said "about 6 grams....about 7 grams etc.) Whereas, Leitz's maximum is 5 grams per serving (in reality 1-3 grams), applicant's minimum is 7 grams of fiber per serving. These are mutually exclusive. **The number of grams of fiber per serving represents a critical difference of applicant over Leitz.**

First office action claims applicant's invention could have been anticipated by Leitz et al. "Leitz discloses a composition which comprises oat, psyllium, guar, and additional fibers [6] to provide a composition which can be administered to mammals to provide a balanced intake of dietary fiber. Applicant submits that applicant's invention could not have been anticipated by Leitz, as Leitz teaches fiber balance and 9 different specific fibers being required. Applicant can make invention with as few as 3 fibers and there is no fiber balance required, nor does applicant use the 9 mandatory fibers Leitz teaches. Applicant's invention could not have been anticipated by Leitz because Leitz teaches high levels of fiber are dangerous and that 5 grams per serving of fiber should be a maximum. Applicant wishes to stress that Leitz prefers only 1-3 grams of fiber per serving! Applicant serves a minimum of 7 grams of fiber per serving and this is exactly

opposite what Leitz teaches. **Applicant's invention cannot be anticipated by Leitz when applicant doesn't follow any of Leitz's teachings.**

Examiner discusses that Leitz teaches a flavoring agent can be added to make a liquid dosage. Starch may be added and finally that soluble fiber in Leitz's formula is associated with a reduction in LDL and serum cholesterol.

Applicant respectfully makes these observations. Leitz teaches the use of a non-toxic inert carrier that typically accompanies the active ingredient of his compositions. He gives an example of starch. (column 4 lines 45-65). Applicant's novel structure does not require inert carriers, starch, etc. Applicant's novel physical structure does not use inert carriers and has no interest in doing so. Leitz, states that his compositions are typically accompanied by these inert carriers, and he also teaches binders, disintegrating agents, and lubricants. Applicant has no need for any of these materials which further shows the novelty of applicant's structure over Leitz.

Examiner stated that Leitz "additionally disclose that the soluble dietary fiber in their composition is associated with a reduction of low-density lipoproteins and serum cholesterol (column 1 lines 45-55). Applicant states that Leitz does not state that his composition lowers LDL and serum cholesterol, but rather that "soluble dietary fiber is associated primarily with a reduction in LDL and serum cholesterol...". Applicant submits that Leitz teaches that it generally accepted that soluble fiber lowers LDL and serum cholesterol, but cautions that there is no proof or method to show that Leitz composition actually does lower cholesterol. As a lipid expert, applicant submits that it cannot be assumed just because a formulation contains soluble fiber that it will in fact lower cholesterol, or lower it significantly. As evidenced by the national guidelines discussed later in this amendment, 5-10 grams of soluble fiber per day resulted only in a 5% drop in LDL. There is no proof that Leitz combination of fibers, the quantity delivered, the interaction of inert carriers, binders, and lubricants would actually lower cholesterol in an organism. Furthermore, he provides no method to do so. **Applicant submits that Leitz should**

not be credited for lowering cholesterol when there is no proof or reason to expect his composition can with all the unanswered variables (interaction of inert carriers, binders, interplay between the various fibers, etc.)

Applicant on the other hand has documented dramatic cholesterol benefits as well as cardiovascular risk reduction along with numerous other benefits that Leitz does not.

Applicant teaches and provides proof that his invention reduces cardiovascular risk and provides specific proof of LDL reduction, HDL elevation, triglyceride reduction, and high-sensitivity C-reactive protein reduction. Leitz does not address the HDL, triglycerides or high sensitivity C-reactive protein levels, nor does he offer reduction in cardiovascular risk.

INDEPENDENT CLAIM 24 RECITES NOVEL PHYSICAL FEATURES OVER LEITZ UNDER SEC 102.

Claim 1 has been rewritten as new claim 24 to more clearly show the physical composition.

Applicant's independent claim 1 rewritten as claim 24 clearly defines novel physical structure over Leitz under Sec. 102.

Claim 24 recites: An orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving, comprising

- (a) a mixture of guar, oat, and psyllium fibers, and
- (b) at least one flavoring agent

Applicant teaches an ultra-high fiber (at least 7 grams per serving) supplement that can be made with 3 specific fibers, and a flavoring agent.

Leitz teaches **against a high fiber** composition due to risks, and concerns of mineral and nutrient depletion. Leitz instead teaches a "modest" fiber intake and a **maximum of 5 grams of fiber per unit-of-use [serving]**. Leitz prefers even smaller amounts of fiber, 1-

3 grams per serving, except in a beverage which he prefers 2 grams. **Applicant's total fiber weight per serving is very different than Leitz, applicant teaches a MINIMUM of 7 grams whereas Leitz teaches a MAXIMUM of 5 grams.** Another physical difference is that applicant has specified that **only 3 fibers** (guar, oat , and psyllium) are needed. Leitz teaches **9 different fibers are required** in his detailed description of his invention. Column 3 including Table 1 detail the need for 9 different fibers. Table 1 even shows that the individual range of each fiber is a **minimum of 1% of the composition proving all listed fibers are necessary.** Applicant wishes to point out that Leitz details a balanced fiber composition that is "balanced" due to the variety of the 9 different fibers. "Thus, three preferred fibers were selected for each group and the preferred balance of each fiber type was determined. The **variety of different fiber components were selected to obtain a balanced fiber composition.** A balanced fiber composition generally has a good variety or range of types of fiber" (column 3 lines 40-47) **In contrast to his own balanced composition, Leitz claim 1 states ... "at least one** of the fibers from the fruit and vegetable group is selected from the group consisting of lemon, acerola, and carrot, ...where in **at least one** of the fibers is selected from the cereal group is selected from the group consisting of corn bran, barley bran and oat bran and**at least one** of the fibers from other than the fruit, vegetable and cereal groups is selected from the group consisting of soybean bran, psyllium seed husk and guar gum. ..." (column 6 lines 20-37) .

Applicant feels it is contradictory to detail the need for 9 fibers and teach how they provide the novelty of a "balanced fiber composition" and then claim that only one fiber from each of the 3 groups is necessary. Applicant acknowledges that the term "at least one" could include all his fibers, however "at least one" also means his fiber composition could be made with as few as one fiber from each group. Applicant wishes to point out to the examiner that the claim is incorrectly written and **both serves and contradicts** his detailed description. Applicant wishes examiner if in agreement to provide Leitz only the narrowest interpretation of his composition. . There are many other physical differences. **Leitz requires 30-48.5% of the total fiber weight to come from the fruit and vegetable group.** Applicant does not require fibers from this group. Leitz

requires fiber from acerola, carrot and lemon as detailed in his detailed description and Table 1. Applicant does not require any fibers from acerola, carrot or lemon, nor does he require all three. **Applicant does not require fruit and vegetable sources of fiber, nor the specific acerola, carrot or lemon fibers. Applicant does not require specific percentages of fruit and vegetable fibers. Leitz teaches against more than 5 grams per serving, and following his percentages of Table 1, 17.8% of the total fiber of his balanced fiber composition is due to guar, oat and psyllium.** Taking his maximum fiber concentration of 5 grams per serving and multiplying by 17.8% (the percentage of guar, oat and psyllium in his formulation) gives **less than 1 gram cumulative fiber weight** from the guar, oat and psyllium fibers. $17.8\% \times 5 \text{ grams} = 0.89 \text{ grams}$ total fiber weight of guar, oat, and psyllium. **Applicant's formulation is physically different in that applicant's formulation could be 100% guar, oat, and psyllium and contain at least 7 grams of fiber per serving of these 3 fibers.**

Claim 24 recites "at least 7 grams of fiber per serving." Leitz teaches "modest" fiber intake and has a **maximum of 5 grams** per serving, but prefers even smaller fiber amounts, specifically 1-3 grams and 2 grams per serving if it is a beverage. Applicant's novel physical structure is different than Leitz. Applicant has a **minimum of 7 grams of fiber per serving**; Leitz has a **maximum of 5 grams of fiber per serving**. **These concepts are mutually exclusive and 180 degrees opposite each other.**

Claim 24 recites "comprising a mixture of guar, oat and psyllium". Applicant requires only these three fibers. Leitz includes these three fibers, but requires a minimum of 9 fibers from his detailed description. Leitz teaches these 9 fibers are special and create the balance in his formula allowing for a modest level of fiber intake to provide health benefits. Even though both applicant and Leitz use guar, oat and psyllium, the two inventions are very different. Leitz is a balanced modest fiber supplement that requires 9 different fibers with attention to specific ratios of each. Applicant is an ultra-high fiber (at least 7 grams per serving) supplement that requires only 3 fibers, and has nothing to do with ratios or

balance. Furthermore, Leitz requires very specific fibers that applicant does not even use such as acerola, lemon and carrot pulp, corn bran, barley bran and soy bran. The number of grams of fiber per serving do not overlap instead they are mutually exclusive.

Claim 24 recites “at least one flavoring agent.” Applicant **requires** at least one flavoring agent, and this allows for applicant to create a pleasant tasting, zero calorie beverage by admixing water. Leitz does not require a flavoring agent, and mixing his bulk fiber powder **requires a liquid food product such as milk or orange juice “to ease administration”**. (column 5 lines 41-44). Leitz does not teach that his composition could be made into a beverage with water, rather instead it requires a liquid food product to ease administration. Leitz only **recommends 2 grams of fiber** per beverage serving and this is important as it shows that he does not recommend the 5 gram maximum, nor even the 3 gram preferred amount of fiber he teaches. Applicant’s novel physical structure allows for a water to be admixed to the supplement of claim 24 and a zero calorie pleasant tasting beverage is created that has at least 7 grams of fiber per serving. Furthermore, Leitz typically has inert non-toxic carriers associated with his composition. Applicant does not.

There are many other differences in physical structure that could not have been anticipated by Leitz. Leitz prefers a tablet, chew tablet or bulk form. **He does not teach a pudding or snack bar**. Applicant teaches to make a beverage, a zero calorie beverage, and a variety of semisolid and solid comestibles not anticipated by Leitz.. Applicant details how the snack bar and puddings are used, and also offers the ability of making other solids such as a wafer and dog bone.

Therefore, applicant submits that it is clear beyond doubt that claim 24 recites novel physical features over Leitz and thus clears Leitz under Sec. 102

**THE NOVEL PHYSICAL FEATURES OF CLAIM 24 ARE
UNOBVIOUS OVER LEITZ UNDER SECTION 103**

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art.

Applicant submits that the above novel physical features of claim 24- including the ultra-high fiber (at least 7 grams per serving) composition comprising three specific fibers guar, oat, and psyllium each with specific physical characteristics and properties and the addition of at least one flavoring agent is unobvious over Leitz for a variety of reasons listed below. Applicant notes that Leitz teaches a balanced fiber formulation to use as an adjunct to the diet, modeled after the basic food groups to provide fiber that approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins and fats (column 4 lines 30-36). To create this balance, Leitz teaches 9 fibers of which a minimum of 30% of the total fiber weight must come from fruit and vegetable fibers. He also teaches the formulation must contain fibers from 3 groups, fruit and vegetable, cereal, and other. Each group should have ideally three fibers in it. **Central to his formulation** is the idea that a balance of fibers can provide the benefits of fiber at a **modest dose of fiber**. By avoiding a high dose of fiber, Leitz teaches you reduce risk of fiber and risk of fiber preventing absorption of other nutrients. **It is unobvious to look at Leitz's invention and make an invention that is not balanced, does not need fruit and vegetable fibers, is not modeled after the carbohydrates, proteins and fats in a balanced diet, and that serves ultra high dose (7 grams or greater) fiber per serving—because he teaches against all this.**

Applicant's invention's ability to provide very high doses of fiber in a unit dose of administration without inert carriers, binders, lubricants, or excipients and provides very important, valuable, and unexpected new results that dramatically improve mammals' (and especially a human's) health. This clearly proves applicant's novel structure is unobvious under Leitz.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PRODUCES UNEXPECTED RESULTS.

Applicant's invention has novel physical structure comprising 3 guar, oat, and psyllium, each with their own specific physical characteristics, and administered in an ultra-high fiber (at least 7 grams per serving) dosage. The total fiber weight must be at least 7 grams per serving and must include a flavoring agent. Applicant, a board certified internal medicine doctor and expert in advanced lipid treatment has noted several unexpected results amongst patients and users of his invention.

- (a) Safe, fast, easy weight loss occurs even in individuals who claim they have failed all diets. It is unexpected to see weight loss in individuals who have failed all other diets. Applicant has witnessed steady weight loss in his patients, and has received numerous comments regarding successful weight loss in individuals who have stated they failed all previous diets. Applicant's extremely high reorder rate is further proof of successful weight loss. Applicant's invention works better than other weight loss products and is safer because it does not contain dangerous stimulants. **Leitz's balanced fiber composition is a diet adjunct, not a weight reduction formula.** Leitz talks about the benefits of using higher dose fiber aiding in weight reduction but teaches it is not without risks and that is why he serves a "modest" not a high level of fiber (column 1 lines 56-67). Leitz offers no method, means or proof his invention will even lead to weight loss. Applicant's invention produces safe and effective weight loss and is seen as a benefit of Leitz's invention. .
- (b) Weight loss occurs without need for food restriction and exercise. All diets not using orally consumed stimulants combine food restriction and exercise as a necessary part of the diet. Applicant's invention promotes satiety that is long lasting and curbs appetite so that less food is consumed despite eating the individual's normal diet. Applicant believes novel physical structure allows weight loss to occur by other mechanisms described in specification as well. Applicant's invention works much better than other weight loss products because the need for will power to restrict certain foods is unnecessary, and the individual does not have to exercise. Leitz teaches his composition is an adjunct to the diet that provides balanced fiber, he does not teach weight loss will occur. Applicant's

invention is specifically designed to maximize health benefits of fiber especially weight loss.

(c) Dramatic reduction in the risk of heart disease due to one or more factors including reversal of metabolic syndrome, weight loss, improvement in cholesterol, triglycerides, lipids, high sensitivity C-reactive protein and homocysteine. Applicant, a physician, has documented marked reduction in risk of cardiovascular disease in numerous patients, and users who have communicated with applicant. Applicant has documented reversal of metabolic syndrome, spectacular weight loss, and improvement in all lipid parameters as well as non-lipid cardiac risk factors homocysteine and high sensitivity C-reactive protein. Applicant has documented new and unexpected results in improvement of lipid parameters. American doctors are taught to observe national guidelines for treatment of lipid disorders. These guidelines are based on the National Cholesterol Education Program Adult Treatment Program III guidelines (NCEP ATP III 2001 V 20-21) . NCEP ATP III teaches that 5-10 grams of soluble fiber only can lower LDL by 5% (NCEP ATP III V20-21). **Applicant has documented LDL drops of over 100 points or reductions of up to 60%. It is unexpected to achieve a 60% reduction in LDL cholesterol when national guidelines teach only 5% reduction.**

Additionally, applicant has documented **triglyceride reductions of up to 82%.**

HDL cholesterol, the good cholesterol, serves as a reverse cholesterol transport. The higher the HDL level, the lower the risk of heart disease. Each one point increase in HDL correlates with a 3-4% reduction in heart disease. Applicant has documented **HDL rises as high as 22 points**, this is **unexpected** as the NCEP ATP III guidelines (V-20) show that soluble fiber **reduces** HDL. "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a **reduction** in HDL cholesterol concentration (Anderson

1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a).

Applicant's unexpected dramatic cholesterol improvements have resulted in numerous patients reducing their cholesterol medication, or eliminating the need for them altogether. In the most dramatic cases, patients have eliminated the need for 3 cholesterol medications that were at maximum doses! Leitz does not teach his composition can reduce or eliminate the need for cholesterol medications. Applicant produces new and unexpected results over Leitz.

Applicant has documented dramatic improvement in reducing cardiac inflammation as judged by high sensitivity C- reactive protein levels. Applicant's formula has taken people in the two highest levels of inflammation and reduced them to the lowest levels of inflammation. This correlates with a quintile 4-5 improved to quintile 1 greatly reducing the risk reduction in cardiovascular disease. Leitz does not teach improvement or even mention high sensitivity C-reactive protein. Applicant produces new and unexpected results over Leitz.

Leitz does not teach cholesterol improvement with his invention, instead he states it is generally accepted that soluble fiber lowers LDL lipoprotein and serum cholesterol. There is no method, means, or proof his actual composition would result in any lipid parameter improvement. Leitz composition containing soluble fiber cannot even be assumed to aid cholesterol as certain fibers, at certain doses are needed to cause improvement, and there is no proof that his specific fibers or dosages would work. It is totally unexpected when national guidelines and research quote soluble fiber can reduce LDL by 5% to get up to 60% reductions. Furthermore, no researcher could have anticipated applicant's invention could reduce the need for cholesterol medications or eliminate the need all together, especially when an individual required maximum dose of 3 cholesterol medications.

Leitz does not teach improvement in HDL. It is totally unexpected when national guidelines and research quote soluble fiber reduces HDL to get up to a 56% improvement. Applicant produces new and unexpected HDL results over Leitz..

Leitz does not teach improvement in high sensitivity C-reactive protein. Applicant is unaware of research showing fiber lowers high sensitivity C-reactive protein yet applicant's invention has improved high sensitivity C-reactive protein in many individuals taking the invention, and some have received maximal improvement. Applicant produces new and unexpected results in high sensitivity C-reactive protein over Leitz.

It is unobvious that ultra high dose fiber per serving (7 grams or greater) can be delivered in a well tolerated non-dangerous form. Applicant further proves this by the NCEP ATP III 2001 guidelines which show that previous research delivered 5-10 grams of fiber per day maximum. (V20-21). **It is also unobvious that ultra high fiber could be delivered without supplemental minerals or nutrients. Most importantly it is unobvious that 7 grams of fiber or greater could be provided in a beverage form without special processing or inert carriers that does not immediately gel.**

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Leitz. These include safe, easy weight loss, and dramatic reduction in risk of cardiovascular disease, improvement in cholesterol, lipids, triglycerides, and high sensitivity C-reactive protein. This clearly proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED UNWORKABILITY.

It is unobvious that more 7 or more grams could be delivered in a serving one or more times daily. Leitz teaches against high dose fiber because it interferes with the absorption of nutrients (column 1 lines 60-63) Leitz teaches a fiber unit dose of up to 5 grams, but recommends 1- 3 grams per unit for administration [serving] and 2 grams if it is in beverage form (column 5 lines 42-44 and 58-63) . Applicant wishes examiner to especially note that Leitz dropped his recommended fiber gram weight per serving from 3 to 2 grams for a beverage. Applicant believes this is due to the difficulty in getting fiber to stay in solution without gelling. Applicant's invention has novel physical structure comprising guar, oat, and psyllium with specific physical characteristics, at least one flavoring agent, and administered in a minimum of 7 gram of fiber per serving dosage. Applicant's invention overcomes 2 problems taught by Leitz, the problem of delivering high dose fiber without risk to the user, and the problem of delivering more than 2 grams in a beverage. Applicant overcomes the assumed unworkability by allowing an individual to safely consume 7 or more grams per serving one or more times daily and without the need for nutrient supplementation. Applicant notes **in over one year's worth of use, there have been no safety issues, no need to supplement minerals or nutrients, and users have had no serious side effects.**

Applicant's invention's ability to **safely deliver a minimum of 7 grams of fiber per serving to a mammal without the need for nutrient supplementation** clearly proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

It is also unobvious that 7 or more grams of fiber per oral unit dose could be delivered in a liquid beverage. Those skilled in the prior art know that putting fiber in a liquid or mixing various fibers in liquid causes the fibers to gel. Increasing the concentration of fiber speeds gelling. It has been assumed that a high fiber drink could not be made as it would be like swallowing jelly instead of a liquid. **Leitz** teaches his fiber invention can be used up to 5 grams per serving, but **recommends only 2 grams** when bulk powder is added to a beverage. (column 5 lines 40-44) Applicant believes Leitz teaches only 2 grams of fiber per beverage is due to the unworkability of putting higher doses of fiber in solution. Up until applicant made his invention, Leitz and

others had not figured out how to deliver 7 grams or greater of fiber in a liquid beverage that does not immediately gel. Leitz also teaches his composition is typically associated with inert nontoxic carrier materials. (column 4 lines 45-52). Applicant's novel physical structure allows liquids to be added to the fiber powder that creates a beverage that is pleasant tasting and does not immediately gel. Applicant's invention does not require inert materials, carriers or special processing. The commercial success of this invention confirms the novelty.

Applicant's invention's ability to put 7 grams or greater of fiber per serving in a liquid beverage without immediately gelling and without danger or risk to the user proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED INSOLUBILITY.

Up to present, those skilled in the art have avoided high doses of fiber due to side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Leitz column 1 58-63). Leitz specifically teaches that "higher intake of dietary fiber is not without risks"...and attempts to maximize the benefits of fiber at only MODEST levels of intake. (column1 lines 55-67).

Applicant, a board certified internal medicine physician, has communicated with numerous patients and buyers of his invention who take more than 14 grams of fiber per day, without significant side effects or any evidence of nutrient or mineral deficiency. Up to now, Leitz and others skilled in the art felt high dose fiber necessitated mineral and nutrient supplementation. Applicant's invention has solved this problem and removed the necessity for nutrient and mineral supplementation.

Applicant's invention's ability to deliver higher doses of dietary fiber (7 grams or greater of fiber per serving) safely and without danger or risk proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

Leitz teaches that soluble fiber is associated with a reduction in LDL and serum cholesterol as well as improved glucose in the short term. (column 1 lines 52-55) Leitz teaches that higher doses of fiber MAY aid in weight reduction. (column 56-58.) Nowhere in Leitz's patent does he teach HIS invention reduces cholesterol or aids in weight reduction. One must assume he does not aid weight reduction as he states higher dosages of fiber are needed and he only provides modest fiber. (Column 1 lines 55-67). Leitz provides no method, means, or proof that his composition improves cholesterol or offers weight reduction. With Leitz composition these 2 benefits are unworkable. Applicant provides weight loss and cholesterol benefit showing his novel structure has overcome unworkability.

Applicant's invention with novel physical structure allows delivery of at least 7 grams of fiber per serving, safely, and without risk or danger to the user. Applicant also provides dramatic weight loss and cardiovascular risk reduction/ cholesterol benefits for the user. Applicant provides a solution to obesity, dyslipidemia, and the dangers of high fiber consumption proving that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF ELEMENT(S)

Leitz's invention requires fibers from 3 different groups to provide a balanced fiber adjunct to the diet modeled after the basic food group to sound nutrition. (column 2 lines 43-45) Leitz recommends 9 fibers with at least 30% from the fruit and vegetable group, 30% minimum from the cereal group, and 3-40% from the non-fruit, non-vegetable and non-cereal group. (column 1, table 1). His fiber invention is further associated with non-toxic, inert carriers. (column 4 lines 46-49). Leitz claim 1 states at least 1 fiber from the fruit and vegetable group consisting of

lemon, acerola, and carrot, at least one from the cereal group consisting of corn, oat and barley bran, at least one from the other (non-vegetable/fruit , non-cereal) group consisting of soybean bran, psyllium seed husk, and guar gum.

Applicant's invention omits many elements. Applicant's invention does not need balanced, fruit and vegetable fibers, nor does it need 3 fibers from each group that Leitz teaches in his detailed description. Applicant does not need any of the fruit or vegetable fibers. Applicant **removes the need for 6 of the fibers** that Leitz teaches are necessary. Applicant's invention does not need inert carriers. Whereas Leitz teaches a complicated formula (column 1 table 1), applicant teaches a much simpler formula that omits many elements of Leitz.

Applicant's invention's omission of several of Leitz's elements proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS.

See attached Declaration Under Rule 132.

Applicant's invention is novel and unobvious in a field that is a crowded art.

The benefits of fiber are well accepted. Fiber supplements are a crowded field, therefore any step forward however small should be regarded as significant. Leitz does not provide information that **his** balanced fiber composition improves cholesterol or reduces weight. He does not provide a method, means, or specific information that his composition offers any benefit of weight reduction or cholesterol improvement. Applicant acknowledges he does mention general benefits of soluble fiber in lowering LDL lipoprotein and serum cholesterol, but one cannot assume that his composition, with his specific fibers, and specific gram amounts, and the potential interactions between binders and inert carriers, would provide these benefits. Even the best fiber regimen that researchers could postulate only offered a 5% reduction of LDL

cholesterol (NCEP ATP III 2001 V20-21). Leitz provides a good balance of fibers based on the basic food group model and his invention is used as an adjunct to a diet. (column 2 lines 42-44, column 4 lines 34-37.) Leitz teaches that high fiber has benefits but also risks, so he teaches ONLY modest levels of fiber intake. (column 1 lines 65-68).

Applicant's invention as listed in claim 24 provides several steps forward over Leitz. Applicant's invention provides dramatic weight loss and cardiovascular risk reduction, as well as dramatic improvement in cholesterol, lipids, triglycerides, high sensitivity C-reactive protein, homocysteine, glucose metabolism, digestive diseases, metabolic syndrome and provides a number of other health benefits.

Applicant's invention's numerous health benefits provided over Leitz's fiber composition proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND OFFERS AN UNAPPRECIATED ADVANTAGE.

Applicant's invention according to claim 24 offers several unappreciated advantages. Leitz teaches to only provide a modest dietary fiber level, as higher levels are associated with risks and nutrient depletion.

Applicant's invention provides an ultra-high fiber (at least 7 grams per serving) supplement. This along with the novel structure, provides many unappreciated advantages. Leitz and others skilled in the art, could not have anticipated the dramatic weight loss, lipid benefits and other health advantages such as lowering of high sensitivity C-reactive protein. NCEP ATP III guidelines teach that soluble fiber at 5-10 grams per day provides only a 5 % reduction in LDL cholesterol. These guidelines also teach that HDL is usually lowered. Applicant's invention has lowered LDL by as much as 60% and typically raises the HDL. In a particularly dramatic case the HDL

was raised 22 points (a 56% elevation). (Each HDL point increase is equivalent to a 3-4% risk reduction in cardiovascular disease). These dramatic benefits could not have been anticipated.

Applicant's invention's numerous unappreciated advantages provided over Leitz's fiber composition proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND HAS NOT BEEN IMPLEMENTED.

Applicant's invention is novel and unobvious. If the invention were obvious, if the advantages were obvious, Leitz and those skilled in the art would have surely developed it by now. The fact that Leitz and those skilled in the art have never created applicant's invention indicates it is not obvious.

The fact that applicant's invention was not previously created proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND QUOTED REFERENCE IS MISUNDERSTOOD.

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art. Applicant believes new claim 24 further shows that invention is unobvious and that Leitz as a reference does not apply to applicant's invention.

Leitz is concerned with providing a fiber supplement that includes a balance of fiber sources from the main food groups that is to be used as an adjunct to a diet. (Column 2 lines 37-42) Leitz does not teach how his invention improves cholesterol or how it can be used for weight reduction. He only mentions in general that soluble fiber can lower LDL and serum cholesterol.

Leitz specifically teaches only a modest dietary level of fiber and specifies the range of 0.5 -5 grams, **preferably 1-3 grams**, and in beverage form he teaches **approximately 2 grams per unit for administration [serving]**. (Column 5 lines 40-64).

Applicant's invention is novel and unobvious and is not similar to Leitz . Applicant's invention is a **ultra-high fiber formulation delivering 7 or more grams of fiber per serving**. Leitz does not deliver more than 5 grams per serving and typically is much less, 1-3 grams. Applicant's fiber powder can be made into a beverage, semi-solid or solid and examples of snack bars and puddings are given. The beverage is unique in that it does not immediately gel and the beverage can even be made into a zero calorie liquid drink. Applicant has no interest in providing a fiber balance or a fiber composition modeled after the basic food groups.

Applicant's and Leitz's structure is different and the objects are different. Leitz wants to provide a balanced fiber composition, modeled after the basic food groups as an adjunct to the diet, in modest fiber intake to avoid any risk to the user. Applicant wants to deliver ultra-high fiber (7 gram or greater per serving) safely in one or more doses daily and to optimize weight loss, cardiovascular risk reduction and a variety of other health benefits.

Applicant respectfully feels that Leitz as a reference was misunderstood in respect to applicant's invention. Applicant believes that claim 24 now proves the applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS CONTRARIAN INVENTION OVER PRIOR ART

Leitz teaches to make a **balanced** fiber supplement that is **only modest in the amount of fiber** per serving. Leitz teaches 0.5-5 grams could be used per unit dose serving but prefers 1-3 grams (column 5 lines 60-61) . Leitz teaches it is necessary to model the fiber composition after

the basic food groups and requires fibers in **specific percentages** in each of 3 groups he specifies as fibers from fruits and vegetables, cereal, and non-fruit-vegetable-cereal group. Leitz requires 9 fibers in his invention. It is important to note that Leitz teaches away from a high level of dietary fiber as he is concerned it is dangerous and provides serious risk to the organism (column 2 lines 32-36).

Applicant has no interest in providing balanced fibers. Applicant is only concerned with delivering ultra-high dose fiber at least 7 grams of fiber per serving. **Applicant's invention's physical structure is contrarian to what Leitz teaches.** Applicant requires only 3 fibers, no balance and specifically does not require acerola, lemon or carrot pulp, corn, barley, and soy bran. Leitz **maximum fiber** is 5 grams of fiber per serving, applicant's **minimum** is 7 grams. Leitz requires 30-48.5% of the fiber weight to come from the fruit and vegetable fiber group, applicant requires no fruit and vegetable fibers. Applicant is concerned with optimizing health benefits especially reducing weight and cardiovascular risk factors through delivering ultra-high dose fiber (7 grams or greater per serving) one or more times daily.

Applicant's invention is contrarian to what Leitz teaches and therefore proves that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND BELIEVES LEITZ IS A "PAPER PATENT".

Applicant is a board certified internal medicine physician who has made other nutritional supplements and skin care products. Applicant is aware of most treatments for improving health and preventing disease, whether prescription, over the counter, or through a variety of marketing channels. Applicant is unaware of Leitz's invention in the market place and he believes it is not currently being made or sold and is in fact a 'paper patent'. Applicant believes Leitz's invention was never implemented or commercialized and therefore should be construed narrowly.

Applicant respectfully also feels Leitz should be construed narrowly as Leitz teaches the

necessity of a variety of different fibers to make a balanced fiber composition, then claims in claim 1 as few as 1 fiber from each of three groups. (column 3 lines 40-47) This a contradiction to what he teaches in his detailed description. **Either his balanced fiber composition requires a “good variety or range of types of fiber” or it doesn’t.** Leitz description absolutely requires 9 fibers as evidenced by a minimum individual range of 1% for each, his claim 1 indicates his composition could be made with as few as 3 fibers. Applicant finds Leitz description of his invention to contradict his claim 1. (column 3 lines 44-47.) **Applicant respectfully sees several problems with Leitz’s invention.** Leitz teaches the bulk powder can be mixed with milk or orange juice or that it can be sprinkled on salad or breakfast food. (column 5 lines 41-46). Applicant notes that any food item including milk and orange juice contain calories and using 2 grams [Leitz’s recommended dosage] of bulk powder 1-4 times per day [with orange juice or milk] could result in a significant calorie load, resulting in weight gain, and all the resulting health problems that accompany weight gain. (column 5 lines 40-63). Leitz prefers a tablet as the delivery form. In regard to the tablet, it appears he would put 1-3 grams per serving. (column 5 lines 46-63). Applicant raises potential problems swallowing the size of the tablet that would be necessary to hold 1-3 grams of fiber, and the potential danger of the tablet being swallowed and sticking in the esophageal lower sphincter, and the ability of the compressed tablet to even disintegrate in the stomach (a compressed tablet of fiber would require high compression to hold the tablet together and it may not disintegrate in the stomach due to this high compression.) Leitz teaches a **chew** tablet could be made. Applicant respectfully, suspects a chew tablet would likely gel in the mouth and be unpalatable if it contained 1-3 grams of fiber and was designed to be chewed for a brief period of time. (column 6 lines 3-9). To the contrary, applicant’s invention is sold commercially and is commercially successful.

Applicant believes Leitz’s invention is a paper patent where as applicant’s invention is commercially successful. Therefore, Leitz’s invention should be construed narrowly and this proves that applicant’s novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND NO CONVINCING REASONING IS PROVIDED.

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art. Applicant believes claim 24 further shows that invention is unobvious and that Leitz as a reference does not apply to applicant's invention and that no convincing reasoning exists as to the obviousness of applicant's invention.

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the multiple differences noted over the prior art, would have been obvious thus proving that applicant's novel structure is unobvious over Leitz under Sec. 103.

**INDEPENDENT METHOD CLAIM 53 RECITES NOVEL
PHYSICAL FEATURES OVER LEITZ AND CLEARS LEITZ
UNDER SEC. 102**

Claim 18 was cancelled and rewritten as new claim 53.

Claim 18 was rejected under 35 U.S.C 102(b) as being unpatentable as being anticipated by Leitz et al. (US patent 4,877,627).

Claim 18 has been rewritten as new claim 53 to more particularly define the invention in a patentable manner over the cited art. Claim 53 shows novel structure in its rewritten form over original claim 18 to better show novel physical features over Leitz. Applicant's claim also shows a method claim which Leitz does not.

Claim 53 states:

A method of reducing the risk of developing and aiding in the treatment of cardiovascular disease in a mammal by improving at least one of the following cardiovascular risk

factors, including serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine comprising orally administering a nutritional supplement containing at least 7 grams of fiber per serving to a mammal comprising a mixture of guar, oat, and psyllium and a flavoring agent, and administering said supplement at least one time daily.

Applicant's physical structure is totally different than Leitz and therefore novel over Leitz. Applicant's supplement comprises 3 specific fibers with specific physical characteristics (guar, oat, and psyllium). Applicant requires **only 3 fibers**, a flavoring agent and yet must contain **at least 7 grams of fiber per serving**. Leitz requires 9 fibers, specific ratios, specific fibers and typically uses inert carriers or binders. (Gori teaches that all fibers are not equal, and Leitz teaches that his balanced fiber composition requires 9 different fibers, admixed in a specific ratio. Leitz teaches a 5 gram fiber per serving maximum and prefers 1-3 grams. It would not be reasonable to assume that Leitz wanted more than 5 grams per serving because he teaches against high fiber that he states is dangerous, he prefers 1-3 grams per serving, and if he wanted higher than 5 grams of fiber he would have listed a higher number of grams. Immediately one sees that applicant is novel over Leitz. Applicant's minimum fiber per serving is 7 grams, and Leitz is a maximum of 5 grams (preferably 1-3 grams). These are mutually exclusive and therefore applicant must be novel. Applicant teaches a beverage, semi-solid and solid form of the supplement with special attention to snack bars and puddings. Leitz does not teach pudding, snack bars, wafers, or dog bones, instead he teaches a tablet, chew tablet, granules to be sprinkled on food, or a 2 gram per serving beverage that requires a liquid food product. **Leitz teaches away from a high fiber supplement stating in provides risk and danger to the organism**, applicant teaches an ultra-high fiber (at least 7 grams per serving) supplement. The physical structures are very different.

Applicant is an ultra-high fiber (at least 7 grams per serving) supplement that provides a **method** for reducing the risk and aiding in treatment of cardiovascular disease. Leitz does

not provide a method, means, or any support that his balance fiber composition provides these benefits. Leitz makes a general comment that soluble fiber is associated with lowering LDL and serum cholesterol. **There is no evidence that Leitz lowers LDL or serum cholesterol.** Research provided by NCEP ATPIII (2001 V20-21) demonstrates research using 5-10 grams of specific soluble fibers lowered LDL by only 5%. There is no proof that Leitz fiber composition with his various fibers at various concentrations can provide any significant cholesterol benefit. (As an example, lowering LDL may require more oat, guar, or psyllium than he provides).

Office action states "The composition and methods of use as disclosed in Leitz et al. is seen to anticipate the composition and the methods of use as set forth in claims 1,3,5,6,10-12,18 and 20 of the instant application" (p.6 3rd paragraph). Applicant respectfully disagrees with this statement which is made clearer by new independent claim 53 that more clearly shows the novel physical structure. **Leitz does not provide nor does he claim a method for reducing the risk and aiding in treatment of cardiovascular disease, nor does he provide a method to improve cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Leitz does not provide nor does he claim a composition for reducing the risk and aiding in treatment of cardiovascular disease, nor does he provide a method to improve cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine.** Applicant respectfully does not see how Leitz anticipates applicant's composition or method, in fact, he teaches against applicant's ultra-high fiber (at least 7 grams per serving) unbalanced fiber supplement.

Applicant provides a method for reducing the risk and aiding in treatment of cardiovascular disease in a mammal by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Nowhere in Leitz are lipoproteins, triglycerides, high sensitivity C-reactive protein, or homocysteine discussed. These are not discussed as Leitz did not anticipate his fiber composition could provide

benefit for them. Leitz does not even discuss how his composition can actually lower cholesterol. He makes the assumption that any formula containing soluble fiber will provide cholesterol benefits. This is untrue. **There may not be enough soluble fiber, the right soluble fibers, or their could be a negative interaction between the various fibers, or inert carriers, and binders Leitz uses.**

Applicant's invention has documented reduced risk of heart disease and is being used in the treatment of heart disease. Applicant, an internal medicine physician and recognized lipid expert who teaches other doctors uses his invention in his daily practice and has documented numerous cases of dramatic risk reduction due to lowering LDL cholesterol, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Applicant has documented improvement in all lipoprotein parameters. Applicant has noted invention tends to raise HDL cholesterol sometimes dramatically. Low HDL cholesterol and low high density lipoprotein is an independent risk factor for heart disease. **Applicant's invention has novel physical structure over Leitz and that is why it has produced new and unexpected results.**

National Cholesterol Education Program ATP III guidelines discuss the research behind fiber and cholesterol reduction. As per their guidelines "5-10 grams of viscous fiber per day reduces LDL cholesterol levels by approximately 5 %" (National Cholesterol Education Program Adult Treatment Panel III Report V-20). Applicant, a physician, has been monitoring patients on his invention and has LDL drops of up to 60% (LDL has dropped over 100 points!) Numerous patients have reduced their medications required to treat their cholesterol, and some no longer need medication. In at least one instance, a patient requiring 3 different cholesterol medications each at maximum dose, had great cholesterol results off all medications after 2 months of applicant's invention. The patient continues to take applicant's invention and enjoys excellent cholesterol control without medications. (Interestingly, the patient never achieved satisfactory control on the three medications). Patients typically take one serving (2 scoops in individual doses admixed with water.) This results in 17 grams of fiber the preferred embodiment.

Applicant teaches other doctors advanced cholesterol evaluation and management, and no doctor

would expect these dramatic changes from fiber. Applicant is aware of no medical data that would suggest this kind of improvement with fiber, to the contrary, the medical literature suggests only a 5% improvement..

Another new and unexpected result is the elevation of HDL cholesterol, further reducing cardiac risks. According to National Cholesterol Education Program Adult Treatment Panel III Report V-20 soluble fiber may lower HDL cholesterol. "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a reduction in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a). Applicant has found that his patients typically benefit from an HDL rise. In some cases the HDL rise is very dramatic representing up to a 56% improvement (a 22 point rise). This translates into a 66-88% reduction in heart disease. (It is well known that every 1 point rise in HDL results in a 3-4% reduction in cardiovascular disease).

Therefore, applicant submits that it is clear beyond doubt that claim 18 rewritten as claim 53 recites novel physical structure over Leitz , that the novel physical structure produces new and unexpected results, and that applicant's novel physical structure clears Leitz over Sec 102

INDEPENDENT METHOD CLAIM 53 SHOWS NOVEL PHYSICAL STRUCTURE THAT IS UNOBVIOUS OVER LEITZ AND CLEARS LEITZ UNDER SEC. 103

Claim 18 was cancelled and has been rewritten to new claim 53

Claim 18 was rejected under 35 U.S.C 102(b) as being unpatentable as being anticipated by Leitz et al. (US patent 4,877,627)

Applicant submits that the above novel physical features of claim 53 are unobvious over Leitz under Sec. 103 because they produce multiple new and unexpected results. Applicant wishes to stress that Leitz does not teach that his invention reduces the risk of developing and aids in the treatment of cardiovascular disease in a subject by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Leitz does not even teach his invention will lower cholesterol and he does NOT provide a method of lowering cholesterol. **Leitz only cites that it is generally accepted that soluble fiber lowers LDL and serum cholesterol.** There is no teaching, proof or information that his invention successfully lowers cholesterol. NCEP ATP III (2001 V20-21) guidelines show that 5 to 10 grams of soluble fiber per day lowers LDL cholesterol by 5%. This statement was based on guar, oat, pectin and psyllium being used in 5-10 gram per day dosages. Leitz recommends a serving of up to 5 grams of fiber but prefers 1-3 grams up to 4 times daily. As previously calculated, 0.89 grams total of guar, oat and psyllium would be delivered with the maximum 5 gram of fiber per serving. **There is no reason to expect an individual taking Leitz invention would have sufficient guar, oat, and psyllium fiber to lower LDL cholesterol.**

Applicant submits that the above novel physical features of claim 53 comprising guar, oat and psyllium each with specific physical characteristics, at least one flavoring agent and an ultra-high fiber (at least 7 grams per serving) supplement, produces unexpected results over Leitz. Applicant's novel structure when mixed with water creates a zero calorie beverage that does not immediately gel. The applicant's invention has created numerous new and unexpected results including reducing the risk of developing and aiding in the treatment of cardiovascular disease by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, homocysteine and reductions in cholesterol, triglycerides, high-sensitivity CRP.

Applicant's invention provides a method of reducing the risk of developing and aiding in the treatment of cardiovascular disease in a subject by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine comprising orally administering the seven gram or greater per oral unit dose of fiber supplement in one or more

daily doses. The unique characteristics and specifications of the fiber used in an ultra-high fiber (at least 7 grams per serving) supplement produces new and unexpected results.

Current scientific guidelines teach “5-10 grams of viscous fiber per day reduces LDL cholesterol levels by approximately 5 %” (National Cholesterol Education Program Adult Treatment Panel III Report V-20). Applicant, a board certified internist and expert in lipid management, has noted **LDL Cholesterol levels dropping up to 60%. Further unexpected results are dramatic triglyceride reductions of up to 82%.**

Another unexpected result is that HDL cholesterol typically increases when taking applicant’s invention. Applicant has found that his patients typically benefit from an HDL rise. This rise has been as high as 22 points. This correlates with a 66-88% reduction in heart disease. This could not be anticipated as (National Cholesterol Education Program Adult Treatment Panel III Report V-21). “Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a reduction in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a).

Another unexpected result is the improvement in cardiac inflammation as noted by high-sensitivity C- reactive protein levels. **Applicant has documented dramatic improvement in high sensitivity C- reactive protein where individuals in the highest risk factor group are brought down to the lowest risk factor group, indicating marked reduction in cardiac inflammation and risk of heart disease.** Leitz does not teach improvement or even mention high sensitivity C-reactive protein. The majority of individuals taking applicant’s invention improve their high-sensitivity C-reactive protein some dramatically. Applicant produces new and unexpected results over Leitz.

Leitz notes that it is well established that soluble dietary fiber is associated with a reduction in low density lipoproteins and serum cholesterol. That research supporting this is backed by the

National Education Cholesterol Program ATP III guidelines which has summarized scientific studies on this subject. These guidelines only support a 5 % reduction in LDL cholesterol. There is no proof, or method of cholesterol lowering with Leitz composition. He may not have the right fibers or the right gram weight of specific fibers to actually improve cholesterol. Even at his maximum 5 gram of fiber per serving he still would have less than 1 gram of guar, oat, and psyllium which may be necessary for cholesterol improvement. Applicant's invention has new and unexpected dramatic results in lowering cholesterol, even lowering LDL ten times greater than could be expected.

Applicant's dramatic risk reduction and prevention of cardiovascular disease is a very important, valuable, and unexpected new result which clearly proves the applicant's novel structure is unobvious under Leitz.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO ASSUMED UNWORKABILITY

Up to present fiber was described in the scientific literature as having a rather mild cholesterol reducing effect. NCEP ATP III guidelines are based on a review of the scientific literature and show that LDL cholesterol decreases by 5% with 5-10 grams of soluble fiber. No medical doctor or scientific researcher imagined that a fiber formula could give such dramatic reductions in LDL cholesterol as applicant has witnessed in his medical practice. It appears the studies did not exceed 10 grams of fiber per day due to the fact that people could not tolerate further increases in fiber due to side effects, the difficulty in providing a consumable high fiber product or a combination of the two. Applicant's invention due to its novel physical characteristics provides a way to deliver a minimum of 7 grams of fiber per serving. Applicant's invention makes it easy to administer more than one ultra-high fiber (at least 7 grams per serving) serving per day. Applicant has overcome the difficulty of giving ultra high dose fiber in a palatable manner, and without significant side effects. Applicant's invention provides reduction in LDL

cholesterol, total cholesterol, triglycerides, lipoproteins, high sensitivity C- reactive protein and elevation of HDL cholesterol and lipoprotein.

Therefore, applicant submits that it is clear beyond doubt that claim 53 recites novel features and provides solutions to providing ultra-high fiber (at least 7 grams per serving) safely to a mammal and provides dramatic, and much better LDL cholesterol lowering than could be anticipated by current guidelines, and Leitz and thus clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO ASSUMED INSOLUBILITY

It has been generally accepted for years that fiber can lower LDL cholesterol. NCEP ATP III represents a national panel recommendations for doctors. The panel's recommendation is based on scientific study and literature. The latest recommendations made in 2001 state that 5-10 grams of viscous fiber per day can reduce LDL cholesterol by 5% (NCEP ATP III 2001 V21). No lipid expert has anticipated the dramatic LDL reductions that occur with individuals taking applicant's invention one or more times daily. **Leitz's invention teaches that it is generally accepted that fiber is associated with a reduction in LDL and serum cholesterol but does not teach that his invention specifically lowers LDL, nor does he teach that his invention affects the risk of cardiovascular disease. Leitz does not provide a method for either, nor does he make a claim for either.**

Applicant's invention results in up to a 60% reduction in LDL cholesterol. This is extremely significant, as the 5% reduction noted by the national experts would not result in a significant benefit for most individuals with a lipid disorder. It would not prevent most patients from reducing or getting off prescription medications. Applicant's significant LDL reductions allow many individuals to decrease their prescription medication or eliminate it completely. The failure of Leitz to teach how to dramatically lower LDL indicates that the solution was not obvious. (Leitz never even shows his composition actually lowers cholesterol, and it would be a

mistake to assume just because Leitz contains soluble fiber that he could even result in a 5% reduction, which is an insignificant reduction in the risk of heart disease in most people).

Leitz does not mention HDL cholesterol, lipids, triglycerides, homocysteine, or high sensitivity C-reactive protein. He does not teach his invention could improve any of these risk factors for heart disease. Applicant has documented improvement in each parameter and provides a solution as it was not anticipated that fiber could provide dramatic improvement in these parameters.

Leitz does not provide nor does he claim a method for reducing the risk and aiding in treatment of cardiovascular disease, nor does he provide a method to improve cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Leitz does not provide, nor does he claim, a composition for reducing the risk and aiding in treatment of cardiovascular disease, nor does he provide a method to improve cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine.

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Leitz. These include aiding in the development and reducing the risk of cardiovascular disease, improvement in cholesterol, lipids, triglycerides, homocysteine, and high sensitivity C-reactive protein. This clearly proves beyond doubt that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS

Please see attached Declaration Under Rule 132.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS IN A CROWDED ART

At present there are multitudes of prescription drugs, and over the counter nutritional supplements, and foods that claim to improve cholesterol. Treatment for high cholesterol is a billion dollar industry and a very crowded art. Applicant's invention produces dramatic risk reduction in cardiovascular disease by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Applicant, a practicing physician and lipid expert has been able to lower the amount of cholesterol medications needed or eliminate them completely from many patients using his invention. Leitz provides no method on how his composition could be used to provide any of these benefits. Applicant's numerous benefits should individually be regarded as significant in a crowded field.

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Leitz. This clearly proves beyond doubt that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF AN ELEMENT(S)

Applicant's invention contains guar, oat, and psyllium each having specific characteristics and specifications. Applicant's invention is an ultra-high fiber (at least 7 grams per serving) supplement comprising guar, oat, and psyllium and a flavoring agent. **Leitz's** invention contains 9 fibers and **requires a non-toxic inert carrier to make it liquid.** (Column 4 lines 45-52). Leitz requires 30-48.5% fiber from the fruit and vegetable group, applicant requires no fruit and vegetable fiber. Leitz requires the composition to be 30-48.5% fiber from the fruit and vegetable group, 30-48.5% from the cereal group and 3-40% from the other (non-fruit, non-vegetable, non-cereal group). Applicant does not. Leitz composition is associated with non-toxic inert carriers, applicant is not. Leitz teaches a good variety of different fibers to give a balanced composition, applicant teaches only 3 fibers are necessary, guar, oat and psyllium, none of which are fruit or vegetable fibers.

Applicant's method claim includes the novel structure of claim 24 that shows many of Leitz's required elements are not necessary. The two structures are very different and applicant's invention is therefore novel in that it does not require all elements fundamental to Leitz. Therefore, applicant submits that it is clear beyond doubt that claim 53 recites novel and unobvious structure over Leitz and clears Leitz under Sec. 103

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO UNAPPRECIATED ADVANTAGE

Leitz never appreciated the dramatic cardiovascular risk reduction could occur with his fiber composition; otherwise he would have taught it and claimed it. Applicant's novel structure provides ultra-high fiber (at least 7 grams per serving) and gives unappreciated advantage. Leitz teaches against high fiber due to the risks and dangers associated with it. Applicant's novel structure has produced no significant side effects in over one year of sale of the product, and has produced much more aggressive improvement in serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine than could be anticipated. Previous scientific study showed that 5-10 grams of fiber produced only a 5% reduction in LDL cholesterol (NECP ATPIII guidelines 2001). Leitz and others did not anticipate the dramatic reductions in LDL cholesterol, total cholesterol, triglycerides, lipoproteins, high sensitivity C-reactive protein and elevation of HDL cholesterol and lipoprotein. Instead, Leitz taught there are risks and dangers to providing high fiber intake. Leitz teaches that high fiber prevents absorption of nutrients. Applicant has never needed to provide nutrient supplementation with his invention. Leitz does not anticipate that applicant's invention would reduce or remove the need for prescription medications. Leitz did not anticipate that dramatic risk reduction in cardiovascular disease could be achieved in addition by using applicant's invention to lower high sensitivity C-reactive protein.

Therefore, applicant submits that it is clear beyond doubt that claim 53 recites novel and unobvious structure over Leitz and provides unappreciated advantages that are very valuable over Leitz and clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE LACK OF IMPLEMENTATION

If applicant's invention was in fact obvious, because of its advantages, Leitz and others skilled in the art surely would have implemented it by now. The fact that Leitz and others have not implemented applicant's invention despite its great advantages, indicates that it is not obvious. Leitz teaches high fiber provides risk and danger to the individual, and therefore teaches a modest fiber intake level. Leitz feels a great variety of different fibers are necessary to make a balanced fiber composition that provides general unnamed health benefits. Applicant teaches balance is not necessary and that his ultra-high fiber (at least 7 grams per serving) is not dangerous or risky. Leitz could not have implemented applicant's invention as he teaches how to make a composition that is 180 degree opposite of applicant's. Applicant's novel and very different physical structure could not have been anticipated by Leitz.

Therefore, applicant submits that it is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz and clears Leitz under Sec. 103

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO MISUNDERSTOOD REFERENCE

Applicant respectfully believes that Leitz as a reference provided in the office action was misunderstood. Leitz teaches how to make a balanced fiber supplement that contains a modest amount of fiber per serving (unit for administration). Leitz teaches the balanced fiber supplement is to provide a balanced intake of fiber. (Column 2 lines 60-61).. Leitz offers the general knowledge that soluble fiber CAN lower LDL and serum cholesterol. He does not teach

his invention provides those benefits, and there is no reason to expect it would. Lowering LDL and serum cholesterol require a specific gram weight of a particular fiber or fibers. There is no evidence Leitz provides those requirements. Leitz further does not teach his invention lowers risk or aids in treatment of cardiovascular disease. With current guidelines showing (NCEP ATP III 2001) that scientific research only supports a 5% reduction in LDL cholesterol when taking 5-10 grams of fiber, **it is not expected that Leitz even if he did lower LDL 5%, would have a significant risk reduction in cardiovascular disease in most humans.** Applicant's invention is very different, applicant provides ultra-high fiber (at least 7 grams per serving) one or more times daily. The particular fibers used in particular amounts results in dramatic benefits in reducing risk and aiding in treatment of cardiovascular disease through, improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Applicant further believes that Leitz is a paper patent and was never made. Applicant respectfully doubts whether it is realistic that an individual would be able to take even 5-10 grams of Leitz in bulk form, chewable tablets, or tablets that are swallowed. The fiber he mixes in milk or orange juice can produce a significant calorie load that could overtime lead to weight gain, and even metabolic syndrome-further advancing the risk of cardiovascular disease. Applicant, a practicing physician and expert in lipid management has documented improved serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine in users of the invention.

Applicant respectfully feels Leitz is misunderstood as he may imply that his composition may help reduce cholesterol, but offers no proof, method or claim. One cannot assume that just because a composition contains soluble fiber, that it will lower cholesterol. There is no proof he actually improves cholesterol, or that he can provide a SIGNIFICANT improvement, or that that improvement reduces cardiovascular risk.

Therefore, applicant submits that Leitz is misunderstood because he states a generally accepted fact that soluble fiber lowers LDL and serum cholesterol. It should not be implied that his

invention also provides those benefits. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz and clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PROVIDES A SOLUTION OF LONG-FELT AND UNSOLVED NEED

Lipid disorders is a collective name used to describe a family of medical disorders characterized by cholesterol, triglyceride and lipoprotein abnormalities. Lipid disorders are extremely common with some estimates that 100 million Americans are affected. The great majority of these lipid disorders require prescription drug treatment. Diet and exercise are lifestyle changes that can improve lipid disorders in some people but as any doctor will testify to, compliance is rare. Others who refuse to take medications can try soy protein, plant stanol sterol esters, or viscous fiber but these result in minor improvement that is usually insignificant in reducing risk of cardiovascular disease. The viscous (soluble) fiber can reduce LDL cholesterol up to 5 % based on studies where 5-10 grams were taken daily. (NCEP ATPIII guidelines 2001 V 21). Low HDL is an independent risk factor for cardiovascular disease. HDL is the good cholesterol that serves to take cholesterol off vessels and back to the liver, a process called reverse cholesterol transport. HDL has limited relationship to diet. It is best treated by smoking cessation, exercise, weight loss, and control of insulin resistance. Many lipid disorders are complicated by a low HDL which requires specific medications to help raise it. Many individuals with lipid disorders need combination therapy, one medication to lower LDL, and a second medication that lowers triglycerides and raises HDL. High sensitivity C- reactive protein is protein made by the liver and serves as an inflammatory marker at the heart. The higher the high sensitivity C-reactive protein, the more inflammation that exists in the heart. A high level dramatically increases risk of disease. Cardiovascular disease is an inflammatory process. A blood test is available that determines the level of high sensitivity C-reactive protein in the blood and this serves as an independent risk factor for cardiovascular disease. The blood test results are reported in quintiles, with quintile 1 being the best and quintile 5 being the worst and having the highest incidence of heart disease. Thus, high sensitivity C-reactive protein can tell one's risk of cardiovascular

disease independent of what one's cholesterol result may be. Options for lowering the high sensitivity C- reactive protein include weight loss, exercise, smoking cessation, aspirin, and statin drugs.

For more than 40 years people have been looking for non-drug ways to improve lipid disorders. The majority of patients fear prescription cholesterol medications due to their potential side effects. There has been a long-felt and unsolved need to have a non-prescription oral supplement that can correct lipid disorders. Applicant, a lipid expert and practicing internal medicine physician, has documented dramatic lipid benefits of individuals using his invention. Applicant had noted LDL improvements of **up to 60%**, triglyceride reductions of **up to 82%**, HDL rises of up to 56%, and dramatic improvement in high sensitivity C- reactive protein levels whereby levels dropped dramatically correlating with a dramatic reduction in cardiac inflammation and in cardiovascular disease.

Leitz teaches that soluble fiber is associated with a reduction in LDL and serum cholesterol but does not teach that his invention provides these benefits, nor does he teach that his invention lowers the risk of cardiovascular disease. One cannot assume just because Leitz contains soluble fiber that his composition lowers cholesterol or cardiovascular risk. His composition may not contain enough soluble fiber, or he may not have enough of particular soluble fibers. Even if his composition did lower cholesterol, there is no proof it is of significance, or that it reaches a significant enough level to lower risk of cardiovascular disease.

Applicant's invention has solved the need whereby a variety of lipid disorders including high sensitivity C-reactive protein elevations can be prevented, improved or treated with a non prescription oral supplement. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz and clears Leitz under Sec. 103 .

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT IS A CONTRARIAN INVENTION

Applicant teaches an invention that is actually contrary to the teachings of Leitz.

Leitz teaches to make a **balanced** fiber supplement that is **modest** in the amount of fiber per serving. Leitz teaches the fiber weight per serving is a maximum of 5 grams. He actually prefers a lower dose of 1-3 grams, and further lowers the dose to 2 grams for a beverage (column 5 lines 60-63 and 41-43) Leitz's invention is a balance fiber composition and he stresses the importance of providing a variety of different fibers to provide this balance. He prefers 9 fibers in his invention. Leitz strictly teaches against high fiber because it has risks and can prevent absorption of nutrients. .

Applicant's invention is contrary to Leitz. Applicant has no interest in providing balanced fibers. Applicant is only concerned with delivering ultra-high fiber (at least 7 grams per serving). Applicant is concerned with optimizing health benefits especially reducing weight and cardiovascular risk factors. **Leitz does not teach that his invention offers either benefit.** Leitz does not teach his composition actually lowers LDL or serum cholesterol. Applicant's invention teaches how to make a novel fiber supplement that can provide a minimum of 7 grams of fiber per serving. Applicant's invention teaches a method of **reducing the risk of developing and aiding in the treatment of cardiovascular disease** in a subject by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine comprising orally administering the fiber supplement with novel physical structure in one or more daily doses. Leitz teaches nothing about reducing the risk of developing and aiding the treatment of cardiovascular disease. Applicant, a doctor has documented dramatic improvement in serum cholesterol, HDL, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. The connection between LDL lowering and risk reduction cannot simply be implied. The greater the reduction in LDL the lower the risk of heart disease. Small decreases in LDL do not significantly reduce risk of cardiovascular disease in most individuals with high cholesterol. For example, A person with LDL of 180 would achieve no risk reduction in heart

disease if their LDL was lowered 5% ($180 - 5\% = 171$). The individual still falls in the highest risk category as the cutoff lower risk requires the LDL to be 159 or less. Hence, no significant cardiovascular risk reduction takes place. NCEP ATP III guidelines show only a 5% reduction in LDL cholesterol with 5-10 grams of soluble fiber, **and in most cases this small reduction would not lead to any significant drop in cardiovascular disease.**

Applicant's invention is contrarian to Leitz, as applicant stresses the advantages of having ultra-high fiber (at least 7 grams per serving), and Leitz stresses not using high fiber due to perceived risks and dangers. Leitz teaches balanced composition made with 9 fibers, applicant teaches balance is not necessary and that only 3 fibers are necessary. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz, is contrarian to Leitz, and clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS BECAUSE REFERENCES ARE PAPER PATENTS

Applicant is a board certified internal medicine physician who has made other nutritional supplements and skin care products. Applicant is aware of most treatments for improving health and preventing disease, whether prescription, over the counter, or nutritional supplements. Applicant is unaware of Leitz's invention in the market place and he believes it is a 'paper patent'. Applicant believes Leitz was never implemented or commercialized and therefore should be construed narrowly. Furthermore, Leitz prefers a tablet or bulk form. The tablet can be swallowed or chewed. Applicant raises potential problems with the size of the tablet that would be necessary to hold 1-3 grams of fiber, the potential danger of sticking in the esophageal lower sphincter, the ability of the compressed tablet to disintegrate in the stomach etc. The chew tablet he teaches would likely gel in the mouth and be unpalatable if it contained 1-3 grams of fiber and was designed to be chewed for a brief period of time. (column 6 lines 3-9).

Applicant respectfully believes Leitz does not teach how his composition could lower LDL, serum cholesterol, or be used for reduction in cardiovascular disease. While it is accepted that

fiber can reduce LDL cholesterol NCEP ATP III guidelines show only a 5% reduction of LDL cholesterol when 5-10 grams of soluble fiber is taken. This small of a reduction in LDL cholesterol will not reduce cardiovascular risk in most individuals to any level of significance.

Applicant believes Leitz is not commercially available and respectfully requests that it be construed narrowly. Applicant's invention is commercially available. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz and clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT USES A NEW PRINCIPLE OF OPERATION

Applicant submits that the above novel physical features described in claim 53 produces new and unexpected results over Leitz by using a new principle of operation. With applicant's unique physical structure the fiber supplement can be mixed with water to make a ZERO calorie beverage that does not immediately gel. This ZERO calorie beverage containing 7 grams or more of specific fibers can be used to promote dramatic weight loss or **cardiovascular benefits**. The applicant has also used a new principle in operation in creating an ultra-high fiber (at least 7 grams per serving) supplement that does not require nutrient or mineral replacement. Applicant has created numerous new and unexpected results including safe and easy reduction in the risk of developing and aiding in the treatment of cardiovascular disease in a subject by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine.

Applicant's invention in preferred alternative embodiment is a zero calorie beverage that contains 8.5 grams of fiber per serving, once or more daily. Typically 1 serving (2 scoops of powder) is used daily. This has resulted in a minimum of 17 grams of fiber daily that has produced dramatic lowering of LDL cholesterol, total cholesterol, LDL lipoprotein, triglycerides, high sensitivity C reactive protein, homocysteine, and elevation of the HDL

cholesterol and HDL lipoprotein. **Applicant's invention is so powerful in reducing these cardiovascular risk factors that at times it has normalized cholesterol that could not be normalized on 3 prescription medications that were given at maximum dose!** Leitz and prior art has never attempted to dramatically lower cholesterol using an ultra high fiber dose in a zero calorie beverage. Applicant has blazed a new trail and his invention is novel and unobvious.

Furthermore, HDL cholesterol, the good cholesterol, is an independent risk factor for cardiovascular disease. It is well accepted that for every 1 point rise in HDL a 3-4% risk factor reduction occurs. It is difficult for most patients to raise their HDL cholesterol.. Applicant has found that individuals taking his invention, typically benefit from a rise in their HDL cholesterol. Applicant has even documented a 22 point rise which results in a 66-88% reduction in heart disease. This could not be anticipated as (National Cholesterol Education Program Adult Treatment Panel III Report V-20). . "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a reduction in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a). Applicant has blazed a new trail offering a new method of raising HDL cholesterol by taking the ultra high fiber supplement in claim 53 as a zero calorie beverage in one or more servings daily.

High sensitivity C- reactive protein is an independent risk factor for cardiovascular disease. The risk is independent of an individual's cholesterol level. Limited options exist to lower high sensitivity C-reactive protein. Current treatment requires taking a statin drug, aspirin, smoking cessation, exercise, and losing weight. Applicant has documented dramatic lowering of high sensitivity C-reactive protein from the highest risk groups to the lowest risk groups with individuals using his invention. Applicant's invention is novel and unobvious as he has discovered a new way for patients to lower their high sensitivity C- reactive protein through consuming his ultra high fiber 7 gram of protein or greater beverage once or more daily.

(Leitz's invention does not teach HDL elevation or high sensitivity C-reactive protein reduction and it cannot be implied.) **Leitz does not teach to make a zero calorie beverage. Leitz does not teach to make a beverage containing more than 2 grams of fiber.**

Applicant uses new principles of operation through using an ultra-high fiber (at least 7 grams per serving), and a zero calorie beverage to reduce the risk of developing and aid in the treatment of cardiovascular disease. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz, new principles of operations over Leitz, and clears Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT SOLVES A DIFFERENT PROBLEM FROM LEITZ

Leitz teaches a balanced fiber composition to provide balanced fiber , provide a good balance of fiber modeled after the basic food groups, and to provide a total dietary balanced fiber to an organism. (column 2 lines 31-54). Leitz teaches his composition is an adjunct to the diet. **Leitz does not teach his composition lowers cholesterol or reduces the risk of developing or aids in the treatment of cardiovascular disease.**

Applicant teaches how to maximize weight loss, cardiovascular risk reduction, and to help prevent or treat a variety of health problems. Applicant provides a method of how to reduce the risk of developing and aid in the treatment of cardiovascular disease in a subject by improving serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine . This solves a different problem than Leitz.

Applicant produces significant and even dramatic reduction in the risks of cardiovascular disease. Applicant, a physician, has used his invention in patients and has communicated with non-patient consumers of his product. Applicant, a board certified internist and expert in lipid management, has noted **LDL Cholesterol levels** dropping over 100 points or up to (60%

reduction). Further unexpected results are dramatic **triglyceride reductions** of **up to 82%**. Another unexpected result is that HDL cholesterol typically increases when taking applicant's invention. Applicant has found that his patients typically benefit from a **rise in HDL cholesterol**. This could not be anticipated as (National Cholesterol Education Program Adult Treatment Panel III Report V-20). "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a **reduction in HDL** cholesterol concentration (Anderson 1995)." Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a).

Another unexpected result is the improvement in high-sensitivity C- reactive protein that has been demonstrated in the majority of individuals taking applicant's invention who improve their high-sensitivity C-reactive protein, some dramatically. Applicant has documented dramatic reduction in cardiac inflammation which corresponds with the dramatic lowering of the high sensitivity C-reactive protein levels with users of applicant's invention.

Applicant solves a problem different than Leitz by teaching a method to reduce the risk of developing and aid in the treatment of cardiovascular disease. It is clear beyond doubt that method claim 53 recites novel and unobvious structure over Leitz, solves a problem different than Leitz, and clears Leitz under Sec. 103.

Applicant respectfully refers examiner to *In re Wright*, 6 USPQ 2d 1959 (1988) and *In re Dillon* 13 USPQ2d 1337 (1989). Whereby an inference of unobviousness in favor of the applicant, and the practical result that the PTO's prima facie determination of obviousness was over-ruled and the burden of proof shifted from the applicant to the PTO.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO LACK OF CONVINCING REASONING

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the differences noted over the prior art, would have been obvious.

Leitz does not teach his balanced fiber composition reduces cholesterol, reduces it significantly, or reduces the risk of developing or aids in the treatment of cardiovascular disease. Leitz only mentions that it is generally accepted that soluble dietary fiber is associated with a reduction in low density lipoproteins and serum cholesterol. (column 1 lines 45-55). The general comment that soluble fiber is associated with LDL and serum cholesterol lowering cannot and should not imply that fiber reduces the risk of heart disease without proof that significant reduction in LDL actually occurs. The implication that fiber lowers LDL cholesterol so therefore reduces risk of heart disease is not unconditionally valid. NCEP ATP III guidelines show only a 5% reduction in LDL cholesterol with 5-10 grams of soluble fiber, **and in most cases this small reduction would not lead to any significant drop in cardiovascular disease.** (An individual with an LDL cholesterol of 180 who gets a 5% reduction in LDL then has an LDL cholesterol of $180 - 9 = 171$. An LDL of 171 remains in the highest risk group for risk of cardiovascular disease and no significant reduction takes place.)

Leitz teaches **against a high fiber** level intake due to risks and dangers to the organism. Leitz teaches a balanced fiber composition with very specific requirements. Applicant teaches ultra-high fiber (at least 7 grams per serving) and that no fiber balance is needed. Applicant is contrary to Leitz.

Applicant respectfully does not feel that citing Leitz provides any convincing reasoning toward obviousness of applicant's invention. Applicant does not understand how anyone reading Leitz could have anticipated applicant's invention or would have come up with the contrary invention that applicant has provided.

Applicant's invention teaches a method of reducing the risk of developing and aiding in the treatment of cardiovascular disease in a subject by improving serum cholesterol, lipoproteins,

lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine comprising orally administering an ultra-high fiber (at least 7 grams per serving) supplement in one or more daily doses. Applicant's invention documents both significant reduction and dramatic reductions in serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Applicant, a lipid expert and practicing physician, has documented numerous cases where cholesterol medications have been reduced or eliminated through the daily use of applicant's invention.

THE DEPENDENT CLAIMS ARE A FORTIORI PATENTABLE

Dependent claim 3 was cancelled and has been rewritten as new claim 27

Dependent claim 5 was cancelled and has been rewritten as new claim 30

Dependent claim 6 was cancelled and has been rewritten as new claim 31

Dependent claim 10 was cancelled and has been rewritten as new claim 35

Dependent claim 11 was cancelled and has been rewritten as new claims 26 & 29

Dependent claim 12 was dropped

Dependent claim 20 was cancelled and has been rewritten as new claim 56 and 57

Additional new dependent claims 25, 28, 32,33,34, 36 , 54 and 55

Since independent claims 24 and 53 are shown to recite novel and unobvious subject matter over Leitz, all the dependent claims listed above are a fortiori patentable over Leitz.

Moreover applicant submits that the following dependent claims are independently patentable over Leitz for the following reasons.

Claim 25 provides specific gram amounts for the guar, oat, and psyllium that are much greater in gram weight than Leitz. Leitz maximum combined weight of guar, oat and psyllium is 0.8 grams, applicant's minimum combined weight of the same three fibers is 2.5 grams. This proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 26 shows admixing at least one ingredient allows for a liquid, semisolid or solid. Leitz teaches tablets, chew tablets and bulk powder, and none are semisolid. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 27 teaches additional fibers that can be added and specifies them their solubility. Leitz teaches fibers based on 3 groups, vegetable and fruit, cereal, and other. Applicant does not use these groups and instead uses soluble, partially soluble and insoluble. These provide different means of classifying the fibers. Applicant does not require the ratios of fiber groups which are a necessity with Leitz. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 28 teaches how to make a zero calorie beverage, Leitz does not teach this. Leitz teaches to add his 2 grams of fiber to a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 29 teaches how to make a semisolid or solid especially a pudding, snack bar, wafer or dog bone. Leitz does not teach these comestibles, instead teaches a tablet and chew tablet. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 30 further defines the flavoring agent that is a necessary part of applicant's supplement. Leitz does not require a flavoring agent but could add one. Leitz is associated with a binder, inert

carrier or lubricant, applicant is not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 31 teaches that additional ingredients that improve visual or organoleptic appeal can be added. Leitz does not discuss thickening agents, thinning agents, or emulsifiers. Leitz discusses need for a binder, lubricant, or inert carrier which applicant does not teach. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 32 teaches an antioxidant can be added. Leitz does not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 33 teaches a tea can be added, Leitz does not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 34 teaches vitamins, minerals, coenzymes, electrolytes etc. can be added, Leitz does not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 35 teaches one caloric ingredient can be added including carbohydrates, fats, and proteins. Leitz does not and teaches a preferred tablet, bulk form, or granules all of which would not need a caloric ingredient. These differences, the differences number, type and ratio of fibers needed,

and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 36 shows a preferred alternate embodiment with green tea, multianthocyanadins, folic acid, pyridoxine, locust bean gum, pectin, and at least one sweetener and flavoring agent. Leitz does not teach these. This shows very different structure than Leitz. Leitz teaches very specific fibers and locust bean gum is not one of them. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claim 56 and 57 teach a zero calorie beverage and semisolid and solid food products, none of which Leitz teaches. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

THE REJECTION OF CLAIMS 1-12, and 16-23 UNDER SEC. 103 (a) IS OVERCOME

Claims 1-12, 16-23 have been cancelled and correspond to new independent claims 24, 37, 42, 45, 53, 58 and dependent claims 25, 27, 28, 30, 31, 32, 33, 34, 35, 26, 29 and 44, 47, 55, 56, 57, 60, 61, 62

THE CLAIM OBJECTIONS UNDER 35 USC§103 ON THE COMBINATION OF LEITZ AND GORI HAVE BEEN OBIATED

INDEPENDENT CLAIM 24 RECITES NOVEL PHYSICAL FEATURES AND IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC 103.

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in patentable manner over the cited prior art.

Applicant submits that Leitz and Gori cannot be combined and offers several reasons below. Assuming they could be combined applicant submits the following.

Applicant's invention is an ultra-high fiber (at least 7 grams per serving) nutritional supplement comprising guar, oat, and psyllium and at least one flavoring agent. Applicant's invention can be made into a beverage, semisolid or solid. The semisolid includes a pudding, the solid includes snack bars, wafers, and dog bones. The beverage is the preferred embodiment. Due to applicant's unique and novel physical structure, water can be added to applicant's invention to create a zero calorie beverage that contains at least 7 grams of fiber and does not immediately gel.

Leitz's invention is a balanced fiber composition that serves as an adjunct to the diet. Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non-vegetable, and non-cereal group. (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that **all** of these fibers are needed as different fiber components were selected to obtain a balanced fiber

composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** (Column 1 lines 59-68, and column 4 lines 42-44) Leitz further teaches a unit-of-use form of which he prefers a tablet, or bulk form. Leitz teaches his oral dosage unit [serving] can contain from 0.5-5 grams of fiber, but prefers 1-3 grams and if in bulk powder form for a beverage only 2 grams is recommended. (column 5 lines 41-65). Leitz teaches that his composition typically contains non-toxic inert carriers to aid with oral administration. (column 4 lines 45-51). Finally, Leitz states that it is generally accepted that soluble fiber is associated with a reduction in LDL and serum cholesterol. (column 1 lines 39-55) Leitz does not in any way show that his composition reduces cholesterol, nor does he provide any method of cholesterol lowering.

GORI

Briefly Gori is a food additive containing a balance of 7 different types of fiber and minerals that is sprinkled on foodstuffs throughout the day. The fibers are all selected for their unique properties and benefits they provide and he teaches the importance of combining corn, oat and wheat bran.

Gori's weight control formulation **contains all** the significant dietary fiber components that should be present in a well-balanced natural diet. The substance of the invention is a scientifically balanced formulation of **essential natural fibers supplemented with the major minerals** that the use of such fibers require. Gori's invention is designed to **restore the natural fiber that modern food technology is known to remove** from the processed foods which are consumed. Unlike other known products the Gori's invention is designed **to provide all fiber varieties known to generate specific health effects** deriving from regular fiber intake. He **teaches fibers are not to be considered equal to one another.** Gori's invention is a "food additive" that must be sprinkled on each meal of the day—suggested use is up to 10 packets per day for an average 150 lb individual and proportionally more or less based on body weight. Gori teaches to make a dry powder that is **sprinkled** on food and **contains 0.5-5 grams of fiber and mineral** supplements. Gori further teaches his invention with examples of **2.0 -3.3 grams**

per serving which is a combination of fiber and mineral weight. . Gori's invention must be sprinkled on foodstuff prior to ingesting it.

Gori teaches:

The fiber containing materials must contain **at least oat and wheat bran**. Gori's actual fiber formulation (column 4) teaches oat, wheat, and corn bran are necessary . Gori teaches that the bran fibers are different and that the wheat is necessary as it supplies lignin, and corn is necessary as it supplies hemi-cellulose to the formulation. Gori teaches oat bran does not supply sufficient lignin or pectin to be employed by itself in the formulation, wheat bran is essential. The formulation contains the **major minerals supplements** that use of essential natural fibers require.

APPLICANT'S INVENTION HAS GENERAL DIFFERENCES OVER THE COMBINATION OF LEITZ AND GORI

Applicant is immediately different from both Leitz and Gori even if they could possibly be combined. Leitz and Gori teach away from high fiber and both have a **maximum** of 5 grams per serving, but prefer much less. Applicant's **minimum** is 7 grams of fiber but prefers 8.5 per serving. **Both Leitz and Gori teach a balanced fiber composition requiring ALL dietary fibers components.** Both Leitz and Gori teach that **all** the fibers necessary in a well-balanced diet are necessary. (Leitz column 2 lines 18-22 & Gori column 3 lines 27-29). **Leitz requires 9 fibers and Gori 7.** Applicant teaches that the ultra-high fiber (at least 7 grams per serving) can be made with as **few as 3 fibers** and that no balance of fibers is needed, certainly all fiber components are not necessary. Leitz requires 30-48.5% of total fiber per serving to come from the fruit and vegetable group and Gori requires oat, wheat, and bran in his detailed description.(at least oat and wheat in his claims). **Applicant does not require fiber from the fruit and vegetable group, and certainly not at a 30-48.5% . Applicant does not require wheat or corn brans.** Gori teaches and **requires mineral supplementation.** Applicant does not. Gori's fiber formulation **must be sprinkled on food, so must be eaten with food.** Leitz teaches a tablet, chew tablet, 2 gram beverage in liquid food stuff and granules. Applicant does not teach tablet, chew tablet, or granules to sprinkle on foodstuffs. Applicant teaches comestibles that all

contain at least 7 grams of fiber and can be administered to a mammal as a beverage, zero calorie beverage, pudding, snack bar, wafer, or dog bone. Applicant's formulation can be taken anytime of day and is preferred 30-60 minutes prior to a meal, and can even be used as a meal replacement. Leitz does not teach weight loss, Gori teaches weight control not weight loss **and his formulation requires dieting**. "It is essential to adopt a proper diet, to reduce fats, sugars, and calories in general..." (column 4 lines 10-13). Applicant teaches weight loss and without the need for food restriction, avoidance, or exercise.

THE NOVEL PHYSICAL FEATURES OF CLAIM 24 ARE UNOBVIOUS UNDER SEC. 103

Applicant argues that Leitz and Gori cannot be combined. They are both independent patents that do not suggest they can be combined, they are both referenced that are individually complete, they teach away from a suggested combination, and they cannot be combined based on their requirements.

The following combination of Leitz and Gori would have to contain at least the following based on the two patents:

1. a **maximum** of 5 grams of fiber per serving **preferably 1-3 grams** (both teach risks and dangers of high fiber)
2. at least oat, wheat, and corn brans (Gori) and barley bran (Leitz)
3. the cereal component would have to make up 30-48.5% of the final fiber weight,
4. 30-48.5% fiber from the fruit and vegetable group
5. lemon, acerola, and carrot pulp (Leitz's detailed description and Leitz's definition of a balanced fiber composition containing a great variety of different fibers.)
6. 3-40% of the other fibers not from fruit, vegetables, or cereals
7. mineral supplements manganese, selenium, zinc, copper, iron and calcium (Gori)
8. the physical form would have to be a powder sprinkled on food. This is the only area of overlap between Leitz and Gori.

Applicant is an ultra-high fiber (at least 7 grams per serving) nutritional supplement comprising guar, oat, psyllium plus at least one flavoring agent. Leitz and Gori teach away from high fiber and never recommend more than 5 grams of fiber per serving. Since both prefer 1-3 gram per serving there was no intention of using more than 5 grams per serving. Leitz and Gori require a balanced fiber formula and teach specific fibers are necessary. This means 7 fibers for Gori and 9 for Leitz. Gori also teaches minerals are necessary. Applicant does not use a balance of fibers and can use as few as three fibers. Applicant does not use minerals. Applicant's novel physical structure is novel and unobvious over Leitz and Gori under section 103.

THE REJECTION OF CLAIM 24 ON THE COMBINATION OF LEITZ ET AL., AND GORI ET AL. IS OVERCOME

The first O.A. rejected independent claims 1 and dependent claims 2-12, independent claim 16 and dependent claims 17, independent claim 18, and dependent claim 19-20, independent claim 21 and dependent claims 22 -23 as being unpatentable over the **combination** of Leitz and Gori.

Claim 24 has been rewritten to define patentability over these references, and any combination thereof. Applicant requests reconsideration of this rejection, as now applicable to claim 24 for the following reasons.

- (1) There is no justification, in Leitz and Gori, or in any other prior art separate from applicant's disclosure, which suggests that these references be combined, much less be combined in the manner proposed.
- (2) The proposed combination would not be physically possible or operative.
- (3) Even if Leitz and Gori were to be combined in the manner proposed, the proposed combination would not show all of the novel physical features of claim 24.
- (4) These novel physical features of claim 24 produce new and unexpected results and hence are unobvious and patentable over these references.

THE REFERENCES AND DIFFERENCES OF THE PRESENT INVENTION THERE OVER

Prior to discussing the claims and the above four points, applicant will first discuss the references and the general novelty of the present invention and its unobviousness over the references.

Leitz creates a balanced fiber composition that is used to provide a balanced intake of fiber (column 2 line 60-61). He specifically teaches that **this proper balance is necessary to maximize benefits of fiber at only modest levels of intake.** (column 1 line 65-68). Applicant's present invention is not concerned with balance of fiber, but rather teaching a way to provide extremely high doses of fiber in a palatable form, that avoids the problem of gelling. Leitz teaches that his novel fiber composition is uniquely formulated to approximate the fiber composition found in a **balanced diet containing the recommended portions of carbohydrates, proteins, and fats.** (column 4 line 31-33). Applicant's selection of fiber is not meant to represent a balanced diet and does not have anything to do with the portions of carbohydrates, proteins, and fats. Leitz teaches a **very specific ratio of fibers** for his formulation. He teaches the formulation has fiber derived from fruits and vegetables 30-48.5%, cereal derived 30-48.5% and 3-40% fibers from non cereal and non vegetable sources. (column 2 line 62-68). Leitz further teaches there are three preferred fibers for each group and the preferred balance of each fiber type is taught. This results in **9 fibers** being required to make the balanced composition. (column 3 line 40-45 & table 1 in column 3). Applicant's invention does not require the variety of fibers or the balance of fibers taught by Leitz that provides his novel balance. Leitz also teaches that typically an **inert carrier material** is added and specifies that in his dependent claim as well. (column 4 line 46-49 7 dependent claim 6.) Applicant's invention is novel in that it **comprises 3 fibers** with specific physical characteristics and properties to provide a way to administer ultra-high fiber (at least 7 grams per serving) without special processing or additional ingredients such as inert carriers. Leitz focus of invention is on delivering modest levels of fiber (column 1 line 65-68). He teaches a range 0.5-5 grams and **preferably 1-3 grams.** Although Leitz uses the term "about 5 grams", applicant respectfully

submits that this should not be interpreted to mean more than 5.49 grams as anything higher would round up to 6 grams, and if Leitz wanted 6 grams he would have stated "about 6 grams". Furthermore, Leitz prefers 1-3 grams of fiber per serving and only 2 grams per serving for a beverage. It is not logical to assume that he would use higher than 5 grams of fiber per serving. Applicant teaches ultra-high fiber (at least 7 grams per serving) not modest levels of fiber. Applicant can deliver this ultra high fiber in a safe easy to consume manner that is safe for a mammal.

Gori teaches to make a weight control formulation that uses fiber and minerals to create a dry powder that is sprinkled on food much as salt and pepper is added to food. (column 2 line 23-24 & 64-66). Gori teaches that the dry powder form is put in individual packets containing about 2 grams each. He then teaches an "average person ...of 150 lbs" would sprinkle 10 packets daily. (column 2 lines 44-48). Implied from his description is that a large human would require sprinkling greater than 10 packets per day to control their weight. His invention seems to be focused on an average person controlling their current weight rather than promoting dramatic weight loss. He describes the substance of his invention as a "scientifically balanced formulation of essential natural fibers supplemented with the major minerals that the use of such fibers requires". (column 3 line 65-68). He further clarifies the necessity of providing **all fibers known to generate specific health benefits**, claims that all fibers are not equal, and this his invention contains **"all" the significant dietary fiber components** that should be present in a well-balanced natural diet. (column 3 line 22-28). Applicant's invention does not require all fibers known to generate specific health benefits, nor does it contain all fibers present in a well-balanced diet. Applicant's thrust of his invention is to deliver ultra-high fiber (at least 7 grams per serving) in a convenient to administer form safely to a mammal. Applicant's invention is used to promote dramatic weight loss that does not result in yo-yo dieting. Applicant's invention is used to dramatically lower cholesterol, lipoproteins, triglycerides, glucose, high-sensitivity C reactive protein, and to treat or reverse the metabolic syndrome. Gori teaches that a recommended dosage of his invention is 10 grams per day, 10 packets for an average individual of 150 lbs. **Gori's invention only serves 2 grams per packet**, thus creating a compliance

problem for a 150 lb individual. Implied is that a larger person would have to sprinkle more packets per day. It is well known that medications delivered fewer times per day have higher compliance rates. Applicant's work as a physician has taught him that getting an individual to take medication 10 times per day is not practical and will not get done. The novelty of applicant's claim is that you can deliver a minimum of 14 grams or more of fiber in two servings. Gori's food additive is sprinkled on foodstuff through out the day.. Applicant's invention does not need to be taken with food and in fact can be used as a meal replacement. An object of Gori's invention is to provide an improved weight control product by conveniently adding it to a food stuff (just) prior to ingesting that same food stuff. (Column 2 lines 7-12). Gori believes he can modulate the food moving out of the gut with his invention. Applicant's invention causes dramatic weight loss by creating satiety prior to eating food. Satiety is created through consumption of applicant's ultra-high fiber (at least 7 grams per serving) supplement prior to eating, the individual feels full and then eats less. Gori's method of weight control does not induce satiety, nor does it decrease the calories consumed at a proposed meal. **Applicant respectfully feels that there is no proof that Gori's weight formulation does anything as it requires adopting a proper diet and reducing fats, sugars, and calories. (column 4 lines 10-13)** all of which are known to reduce weight. Gori teaches that minerals are necessary for his balanced fiber formulation that kelates or sequesters minerals in the gut. (column 2 lines 3-7). All his embodiments contain a variety of minerals. Applicant's current invention does not require minerals. Individuals using applicant's invention for more than one year have not demonstrated any mineral deficiency. Minerals are not required.

Applicant has summarized some of the differences between his invention and the cited references Leitz and Gori. Applicant's invention is very different than the two balanced fiber formulas. **Neither cited reference is trying to administer high dose fiber per serving as evidenced by both teaching high fiber has risks and is dangerous, and that is why they have chosen a "balanced formula"** Both references require a great variety of fibers. Leitz requires 9 and Gori 7. Applicant requires only 3 fibers and serves at least 7 grams of fiber per serving. Applicant's fibers have nothing do with a balanced diet, or the basic food groups. Leitz and Gori recommend a maximum of 5 grams per serving, but prefer 1-3, and **Gori's grams**

include the mineral weight and any additional supplements. Applicant's preferred embodiment is a beverage containing at least 7 grams of fiber. Leitz beverage contains only 2 grams of fiber and requires a liquid food product for administration. **Gori requires minerals,** Leitz states typically his fiber components are associated with an inert carrier. Gori's invention is for weight control not for dramatic weight loss. In fact, the only individual he describes in his invention is an average 150 lb subject (which appears to be an average weight for a human not overweight). Leitz invention is concerned with providing a balance of fibers that is modeled after the basic food groups not weight loss. Gori teaches that the balance of his fibers will provide known benefits of fiber. Applicant respectfully disagrees. Applicant a physician and lipid expert submits that reduction in cholesterol requires specific fibers in specific gram amounts. It is possible that Leitz or Gori's blend of fibers, or the addition of minerals is counter productive, it is possible that he is not delivering enough gram weight of certain fibers. As the national guidelines teach, 5-10 grams of soluble fiber results in a 5% reduction in LDL. This is usually not significant enough to reduce the risk of cardiovascular disease. So applicant submits that Leitz and Gori, do not reduce the risk of cardiovascular disease. Furthermore, **Gori requires a proper diet with reduction in fats, sugar, and calories. This "proper diet" may be responsible for all the health benefits that could be associated with Gori including weight control, cholesterol and cardiovascular risk reduction, if it even occurs. Applicant submits that Gori's invention does not offer these health benefits and that is why he requires the diet with reduced fats, calories, and sugar.** Gori also requires 10 packets per day on all foodstuffs throughout the day. Applicant a physician, submits this is a compliance nightmare. Applicant typically delivers 17 grams of fiber in two convenient beverages.

LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR COMBINATION, MUCH LESS THE MANNER PROPOSED

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art § 103

rejection, *the references themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself....*Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled

in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness Only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per**

serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently. Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

"That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention."

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also

improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P. 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra, a “factual basis to support his conclusion that it would have been obvious” to make the combination.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES ARE INDIVIDUALLY COMPLETE

Applicant submits that Leitz and Gori should not be combined because each reference represents a complete and functional patent. Therefore, there is no reason to add or substitute parts of a patent with another patent.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant’s novel physical structure is unobvious and clears Leitz and Gori under Sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE DIFFERENT APPROACHES

Leitz and Gori both propose a balanced fiber supplement, but they both take different approaches. Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that **requires minerals**. They are used for different purposes, as Leitz does not teach weight loss and Gori teaches weight control. They use different approaches to arrive at a balanced formula. **Leitz requires 9 fibers** from each of three groups. **Leitz does not feel wheat bran is important and instead teaches barley bran. Leitz requires acerola, carrot, and lemon pulp. Gori teaches all fibers are different and cannot be interchanged. Gori requires 7 fibers and teaches the necessity of corn, oat, and wheat bran.** Leitz's invention is a balanced fiber composition that serves as an adjunct to the diet. Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non- vegetable, and non-cereal group. (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** Finally, Leitz teaches a variety of unit-of-use administration [servings] in a variety of forms but does not teach it is a food additive to be sprinkled on all foodstuffs throughout the day. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

GORI

Gori's weight control formulation is a balanced fiber formulation containing 7 different fibers. He teaches it **contains all** the significant dietary fiber components that should be present in a

well-balanced natural diet. The substance of the invention is a scientifically balanced formulation of **essential natural fibers supplemented with the major minerals** that the use of such fibers requires. Gori's invention is designed to **restore the natural fiber that modern food technology is known to remove** from the processed foods which are consumed. Unlike other known products the Gori's invention is designed to **provide all fiber varieties known to generate specific health effects** deriving from regular fiber intake. He **teaches fibers are not to be considered equal to one another**. Gori's actual fiber formulation (column 4) teaches oat, wheat, and corn bran are necessary. Gori teaches that bran alone is not a complete fiber. He teaches the bran fibers are different and oat bran is rich in natural gums, the wheat is necessary as it supplies lignin, and corn is necessary as it supplies hemi-cellulose to the formulation. Gori teaches oat bran does not supply sufficient lignin or pectin to be employed by itself in the formulation, wheat bran is essential. The formulation contains the **major mineral supplements** that use of essential natural fibers requires. Whereas Leitz describes the 3 fiber groups and the specific percentages of each, Gori stresses the bran fibers. Gori teaches from the table in column 4 that the fruit and vegetable group amounts to 15% not the 30-48.5% taught by Leitz. He also teaches the cereal group should be 55% not 30-48.5% as Leitz teaches.

Gori's invention is a **"food additive"** that must be sprinkled on each meal of the day—suggested use is up to 10 packets per day for an average 150 lb individual and proportionally more or less based on body weight. Gori teaches to make a dry powder that is **sprinkled** on food and **contains 0.5-5 grams of fiber and mineral** supplements. Gori further teaches his invention with examples of **2.0 -3.3 grams per serving**. **Gori's invention must be sprinkled on foodstuff prior to ingesting it.**

Leitz and Gori take different approaches to describe a balanced fiber supplement—one being a balanced fiber composition, the other a weight control formulation. The two patents take different approaches, teach different fibers to use, and different ratios of these fibers. Leitz does not require minerals, Gori does. These inventions should not be combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TEACH AWAY FROM THE SUGGESTED COMBINATION

Leitz and Gori are two independent patents that teach how to make their individual inventions. They use different approaches and have different main functions. Leitz teaches a balanced fiber formulation to provide a beneficial total dietary fiber balance **modeled after the basic food group approach**. Gori teaches primarily a balanced fiber composition for weight control. They both use a variety of fibers but recommend different percentages of certain classes of fibers. Leitz recommends 30-48.5% fiber from fruit and vegetable group, whereas Gori only 15%. Gori stresses the importance of the cereal group requiring corn, oat and wheat bran, it makes up 55% of his formulation. Gori stresses the importance of **wheat** and makes it essential to his formulation. Leitz recommends corn, oat and **barley** and **does not recommend wheat**. **Leitz teaches that the fibers he picked were carefully selected to provide the desired nutritional benefit. Gori requires specific minerals, Leitz does not.** Leitz requires acerola, carrot and lemon pulp, none of which are taught by Gori. Gori must be sprinkled on foodstuffs throughout the day, this is not required by Leitz. Applicant respectfully submits that these are different patents that require different essential elements, and therefore, teach a difference of opinion. Applicant respectfully does not understand how the differences could be brought into combination. Applicant respectfully submits because they teach away from being combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES BECAUSE THEY ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and certain percentages to make their invention. They are different. Applicant does not understand how two mutually exclusive elements can be combined. Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat,

Leitz teaches barley. Leitz does not require minerals, Gori requires specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group consisting of acerola, carrot, or lemon.** Gori uses the word “consisting of” in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims.** Gori requires a powder to be sprinkled on foodstuffs throughout the day, Leitz does not. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their different requirements. Applicant’s novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE MUTUALLY EXCLUSIVE PATHS

Leitz and Gori cannot legally be combined because they take mutually exclusive paths to reach different solutions to a problem, therefore by implication each teaches away from combining itself with the other. Both teach a fiber composition to provide a fiber balance to mammal. They however teach different requirements are necessary to provide this balanced fiber. Leitz models his fiber composition after the dietary fiber found in the basic food group approach to nutrition, **Gori’s substance of his invention is designed to restore the natural fibers that modern food technology is known to remove from the processed foods (column 3 lines 40-44).** Gori teaches to use brans with other gut influencing substances to formulate a weight control substance. Leitz teaches the balance of fiber based on 3 groups and a variety of fibers within each group. Gori’s formulation must be added to all foodstuffs throughout the day. Leitz does not teach this. **While both Leitz and Gori attempt to provide balanced fiber to a mammal, they use different approaches and this results in different functions.** Leitz does not teach weight control, Gori does. Leitz and Gori should not be combined Applicant’s novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES HAVE CLAIMED FEATURES LACKING

Even if Leitz and Gori could be combined certain claims would not be met. For example, **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Leitz teaches administration 1-4 times per day. Gori requires his invention to be sprinkled on food stuffs throughout the day. Gori requires wheat bran, Leitz teaches barley bran. Gori teaches all fibers are different and cannot be interchanged.** Applicant submits that Leitz and Gori would not meet all their claims if combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED DUE TO THE MULTIPLICITY OF STEPS REQUIRED

The combination requires a series of requirements set forth in the detailed descriptions and claims that makes trying to combine the two very difficult and not obvious. One would have to add wheat to Leitz and still obey the proper cereal ratio. The only fruit that Gori allows is pectin and cutin, and this goes against Leitz carefully selected acerola, lemon, and carrot pulp that provides the fiber balance he teaches. The end result would have to be powder that is sprinkled on foodstuffs throughout the day as Gori teaches. **One would not know how to resolve the difference between the fruit and vegetable total fiber ratio that is mutually exclusive Leitz being 30-48.5% of total fiber, and Gori being 15% or less. Leitz teaches 30-48.5% from the cereal group, Gori 55%.** Great difficulty exists in trying to obey all the requirements of both references with respect to ratios and the great variety of fibers both teach. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

**EVEN IF LEITZ AND GORI WERE TO BE COMBINED IN THE MANNER
PROPOSED, THE PROPOSED COMBINATION WOULD NOT SHOW ALL OF THE
NOVEL FEATURES OF CLAIM 24**

However, even if the combination of Leitz and Gori was legally justified , claim 24 would still have novel (and unobvious) physical features over the proposed combination. In other words, applicant's invention, as defined by claim 24 comprises much more than merely using oat, guar and psyllium.

Applicant's invention uses specific fibers with specific physical characteristics and properties (mesh sizes, viscosities, fat and water absorption). Applicant's novel physical structure allows **7 or more grams of fiber per serving** to be admixed with a liquid to create a beverage that does not immediately gel. Combining the variety of fibers in Leitz and Gori would immediately gel—the expected result. Combining Leitz and Gori does not produce weight loss as Leitz does not teach how weight loss could occur, and although Gori teaches weight control without causing satiety, his formula **still requires reduction of fats, sugar and calories—a diet** itself that can give weight loss. Applicant's invention produces dramatic weight loss in major part due to the satiety that it causes before the meal and for several hours afterward. Gori teaches weight control by the use of 3 different brans that modulate food moving in and out of the stomach. Applicant teaches weight loss by creating satiety with fiber before the meal, so that the mammal feels full at time of the meal, and eats less. This reduction in calories consumed results in easy weight loss that does not require food avoidance or exercise. **Creating satiety prior to mealtime or snack time is an unexpected result. Having satiety that last for several hours after consuming applicant's invention is a new and unexpected result. Being able to lose weight without food avoidance, dieting, or exercise is a new and unexpected result.**

**THE NOVEL PHYSICAL FEATURE OF CLAIM 24 PRODUCES NEW AND
UNEXPECTED RESULTS AND HENCE ARE UNOBVIOUS AND PATENTABLE
OVER THESE REFERENCES UNDER § 103**

Also applicant submits that the novel physical features of claim 24 are also unobvious and hence patentable under § 103 since they produce new and unexpected results over Leitz and Gori, or any combination thereof.

Applicant is a medical board certified internal medicine doctor who has noted unexpected results in his patients.

These new and unexpected results include:

- A) dramatic weight loss without avoiding foods an individual craves
- B) dramatic weight loss without skipping meals
- C) the versatility for invention to be used to skip meals or to consume all meals
- D) the versatility for the invention to prevent or limit snacking
- E) the versatility to make a zero calorie beverage as a snack or meal
- F) The versatility to make a zero calorie beverage that will prevent calorie consumption at a meal
- G) The versatility to make a zero calorie beverage that will prevent caloric consumption at a snack
- H) Safe and healthy weight loss
- I) Easy and sustained weight loss in individuals who have failed all other diets.
- J) Healthy weight loss without the use of dangerous stimulants.
- K) Prevention of obesity related cancers
- L) Prevention and treatment of hypertension
- M) Prevention and treatment of cardiovascular disease
- N) Prevention and treatment of hypercholesterolemia
- O) Prevention and treatment of hypertriglyceridemia
- P) Prevention and treatment of hyperlipoproteinemia
- Q) Prevention and treatment of high sensitivity C- reactive protein
- R) Prevention and treatment of homocysteinemia.

- S) Prevention and treatment of insulin resistance
- T) Prevention and treatment of glucose intolerance
- U) Prevention and treatment of diabetes
- V) Prevention and treatment of sleep apnea
- W) Prevention and treatment of fat induced liver disease (NASH- Non-Alcoholic Steatohepatitis)
- X) Treatment or reversal of the metabolic syndrome
- Y) Prevention and treatment of diverticulosis
- Z) Prevention and treatment of hemorrhoids
- AA) Prevention and treatment of irritable bowel
- BB) Treatment prevention of osteoarthritis
- CC) Prevention of gallstones
- DD) Prevention of constipation
- EE) Prevention and treatment of osteoporosis

UNEXPECTED RESULTS

Applicant's invention produces superior weight loss results to other weight loss methods.

A) individuals who could not previously lose weight have lost weight.

Individuals consuming applicant's invention have remarked that "This is the first time I am able to lose weight", "I have never been able to lose weight before", "This is the easiest way to lose weight". Applicant is a physician who has documented weight loss in his office to confirm these statements.

B) Many individuals have lost more than 30 -50lbs and achieve their ideal body weight.

Applicant a physician, has this documented in his medical office.

C) Individuals lose weight without avoiding foods they like. Most diets require food restriction.

Applicant's invention produces strong satiety prior to the meal so that fewer calories are consumed during a meal, and weight loss occurs. It is unexpected that you can lose weight without dieting.

D) Individuals lose weight without exercising. Applicant's invention cuts calorie consumption enough that exercising is not a requirement to lose weight. Nearly all diets require increased activity to lose weight. It is an unexpected result that you can lose dramatic weight without exercise and without dangerous stimulants.

E) More unexpected results are discussed below (i.e., cardiovascular risk reduction benefits)

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PRODUCES UNEXPECTED RESULTS

Applicant's invention has novel physical structure comprising an ultra-high fiber (at least 7 grams per serving) supplement using 3 specific fibers with specific physical characteristics, and at least one flavoring agent. The novel supplement containing at least 7 grams of fiber per serving can be easily administered to a mammal as a liquid, semisolid, or solid. Applicant, a board certified internal medicine doctor and expert in advanced lipid treatment has noted several unexpected results amongst patients and users of his fiber supplement.

- (a) safe, fast, easy weight loss occurs even in individuals who claim they have failed all diets. It is unexpected to see weight loss in individuals who claimed to have failed all other diets. Applicant has witnessed steady weight loss in his patients, and has received numerous comments regarding successful weight loss in individuals who stated they failed all other diets. Applicant's extremely high reorder rate is further proof of successful weight loss. Applicant's invention is safer because it does not contain dangerous stimulants. Applicant's invention works better than other weight loss formulas as foods do not need to be avoided, and exercise is not necessary to promote weight loss. Applicant's is better than other diets in that it is totally customizable to the eating problem. Some individuals gain weight from snacking, others from overeating at meals. Applicant's supplement can be customized to an individuals own eating problem. **Leitz's balanced fiber composition is a diet adjunct not a weight reduction formula.** Leitz talks about the benefits of using higher dose fiber aiding in weight reduction but teaches it is not without risks and that is why he serves a "modest" not a high level of fiber

(column 1 lines 56-67). Leitz offers no method, means or proof his invention will even lead to weight loss. **Gori is a weight control formula that must be taken by sprinkling on meals 10 times per day. Gori's weight control formula must be combined with dieting in reducing fats, sugars, and calories** (column 4 lines 10-12) . Applicant respectfully submits, one does not know whether Gori's formula gives weight loss or the weight loss is due to dieting and reduction of calories. Furthermore, Gori makes a requirement of sprinkling on foodstuffs 10 times per day. This means calories are consumed 10 times per day and may potentially result in increased consumption of calories and weight gain!. **Applicant's invention produces new and unexpected results over the combination of Leitz and Gori with safe, easy, and many times dramatic weight loss.**

- (b) Applicant's weight loss occurs without need for food restriction and exercise. All diets not using orally consumed stimulants combine food restriction, avoidance, and exercise as an essential to losing weight. Applicant's novel physical structure promotes satiety that is long lasting and curbs appetite so that less food is consumed despite eating the individual's normal selections of food. Applicant believes novel physical structure allows weight loss to occur by other mechanisms described in specification as well. Applicant's invention works much better than other weight loss products because the need for will power to restrict certain foods is unnecessary, and the individual does not have to exercise. **Leitz teaches his composition is an adjunct to the diet that provides balanced fiber, he does not teach weight loss will occur. Gori is a weight control formula that does not teach weight loss can occur without adopting a proper diet and reducing fats, sugars, and calories.** (column 4 lines 10-13) **Applicant's invention produces new and unexpected results over the combination of Leitz and Gori with weight loss that occurs without having to avoid foods, and without exercising.**

- (c) Applicant produces dramatic reduction in the risk of heart disease due to one or more factors including reversal of metabolic syndrome, weight loss, improvement in

cholesterol, triglycerides, lipids, high sensitivity C-reactive protein and homocysteine. Applicant, a physician has documented marked reduction in risk of cardiovascular disease in numerous patients, and users who have communicated with applicant. Applicant has documented reversal of metabolic syndrome, spectacular weight loss, and improvement in all lipid parameters as well as non-lipid cardiac risk factors homocysteine and high sensitivity C-reactive protein. Applicant has documented new and unexpected results in improvement of lipid parameters. American doctors are taught to observe national guidelines for treatment of lipid disorders. These guidelines are based on the National Cholesterol Education Program Adult Treatment Program III guidelines (NCEP ATP III 2001 V 20-21). NCEP ATP III teaches that 5-10 grams of soluble fiber only can lower LDL by 5% (NCEP ATP III V20-21). **Applicant has documented LDL improvements of more up to 60%. It is unexpected to achieve 60% reduction in LDL cholesterol when national guidelines teach only 5% reduction.** Additionally, applicant has documented triglyceride reductions of **up to 82%.**

HDL cholesterol, the good cholesterol, serves as a reverse cholesterol transport. The higher the HDL level, the lower the risk of heart disease. Each one point increase in HDL correlates with a 3-4% reduction in heart disease. Applicant has documented **HDL rises** as high as 22 points. This is unexpected as the NCEP ATP III guidelines (V-20) show that soluble fiber **reduces** HDL. "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans) produces a **reduction** in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a).

Applicant's unexpected dramatic cholesterol improvements have resulted in numerous patients reducing their cholesterol medication, or eliminating the need for them altogether. In the most dramatic cases, patients have eliminated the need for 3 cholesterol medications that were at maximum doses! Leitz does not teach his composition can

reduce or eliminate the need for cholesterol medications. Leitz does not teach cholesterol improvement with his invention, instead he states it is generally accepted that soluble fiber lowers LDL lipoprotein and serum cholesterol. There is no method, means, or proof his actual composition would result in any lipid parameter improvement. Leitz composition containing soluble fiber cannot even be assumed to aid cholesterol as certain fibers, at certain doses are needed to cause improvement, and there is no proof that his specific fibers or dosages would work. Gori suggests his formulation will lower cholesterol based on the knowledge that oat fiber reduces cholesterol and that pectins and gums can lower cholesterol, but does not provide proof his actual formulation can lower cholesterol significantly, and certainly does not demonstrate that it lowers cholesterol enough to actually result in a reduction in the risk of heart disease. Gori's wheat and corn fibers could have a negative effect on cholesterol reduction and may bind to the oat fiber. Gori may not contain enough gram weight of specific fibers necessary to lower cholesterol. Gori requires invention to be sprinkled on food stuffs 10 times per day. This could result in eating additional calories and ultimately weight gain. Assuming Gori does lower cholesterol, it would not be expected to be beyond the national guidelines of 5-10 grams of fiber gives a 5% reduction in LDL, rather insignificant in most individuals and not significantly lowering the risk of cardiovascular disease. Furthermore, no researcher could have anticipated applicant's invention could reduce the need for cholesterol medications or eliminate the need all together, especially when an individual required maximum dose of 3 cholesterol medications

Both Gori and Leitz do not teach HDL elevation or triglyceride lowering. It is totally unexpected when national guidelines and research teach soluble fiber reduces HDL to get up to 22 point improvement. Applicant produces new and unexpected HDL results over Leitz and Gori. **Applicant produces new and unexpected results over Leitz and Gori by dramatically reducing risk of cardiovascular disease by dramatically lowering LDL and triglycerides and raising HDL.**

Another unexpected result is the improvement in cardiac inflammation as noted by high-sensitivity C- reactive protein levels. Applicant has documented dramatic improvement in high sensitivity C- reactive protein where individuals among the highest risk factor groups are brought down to the lowest risk factor group, **indicating marked reduction in cardiac inflammation and risk of heart disease**. Leitz and Gori do not teach improvement or even mention high sensitivity C-reactive protein. The majority of individuals taking applicant's invention improve their high-sensitivity C-reactive protein some dramatically. Applicant produces new and unexpected results over Leitz.

Leitz and Gori teach away from high fiber intake and report that it is dangerous.. Applicant is a contrary invention. It is unobvious that ultra high dose fiber per serving (7 grams or greater) can be delivered one or more times daily in a well tolerated non-dangerous form. Applicant further proves this by the NCEP ATP III 2001 guidelines which show that previous research delivered only 5-10 grams of fiber per day maximum. (V20-21). It is also unobvious that ultra high fiber could be delivered without supplemental minerals or nutrients. **Most importantly it is unobvious that 7 grams of fiber or greater could be provided in a beverage form without special processing or inert carriers that does not immediately gel.**

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Leitz and Gori. These include safe, easy weight loss, and dramatic reduction in risk of cardiovascular disease, improvement in cholesterol, lipids, triglycerides, and high sensitivity C-reactive protein. **This clearly proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.**

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED UNWORKABILITY.

It is unobvious that 7 or more grams could be delivered in a serving one or more times daily. Leitz teaches against high dose fiber because it interferes with the absorption of nutrients (column 1 lines 60-63) Leitz teaches a fiber per serving of up to 5 grams, but recommends 1- 3 grams per serving and 2 grams if it is in beverage form (column 5 lines 42-44 and 58-63) . Applicant wishes examiner to especially note that Leitz dropped his fiber gram weight from 3 to **2 grams** for a beverage. Applicant believes this is due to the difficulty in getting fiber to stay in solution without gelling. Gori teaches away from high fiber by teaching his packets are 0.5-5 grams each, and preferably 3.3 grams each (with weight of minerals in that gram weight). Gori teaches minerals are necessary due to fiber sequestering or kelating minerals. (column 2 lines 4-6). Applicant's invention has novel physical structure comprising 3 fibers with special physical properties, at least one flavoring agent and a minimum fiber weight of 7 grams of fiber per serving.

Applicant's invention overcomes 3 problems taught by Leitz and Gori, the problem of delivering high dose fiber without risk to the user, the problem of delivering more than 2 grams in a beverage and the problem of delivering fiber without having to replace minerals or nutrients. Applicant notes in over one year's worth of use, there have been no safety issues, no need to supplement minerals or nutrients, and users have had no significant side effects. **Applicant's novel physical structure overcomes the assumed unworkability by allowing a mammal to safely consume 7 or more grams per serving 1 or more times daily and without the need for nutrient supplementation and is clearly unobvious over the combination of Leitz and Gori under Sec. 103.**

It is also unobvious that 7 or more grams of fiber per oral unit dose could be delivered in a liquid beverage. Those skilled in the prior art know that putting fiber in a liquid or mixing various fibers in liquid causes the fibers to gel. Increasing the concentration of fiber speeds gelling. It has been assumed that a high fiber drink could not be made as it would be like swallowing jelly instead of a liquid. Leitz teaches his fiber invention can be used up to 5 grams per serving, but **recommends only 2 grams** when bulk powder is

added to a beverage. (column 5 lines 40-44) Applicant believes Leitz teaches only 2 grams of fiber per beverage is due to the unworkability of putting higher doses of fiber in solution. Up until applicant made his invention, Leitz and others had not figured out how to deliver 7 grams or greater of fiber in a liquid beverage that does not immediately gel. Leitz also teaches his composition is typically associated with inert nontoxic carrier materials. (column 4 lines 45-52). Gori does not teach a beverage, instead his fiber is a powder sprinkled on foodstuffs. Applicant's novel physical structure allows liquids to be added to the fiber powder that creates a beverage that is pleasant tasting and does not immediately gel. Applicant's invention does not require inert materials, carriers or special processing. The commercial success of this invention confirms the novelty.

Applicant's invention's ability to put 7 grams or greater of fiber per serving in a liquid beverage without immediately gelling and without danger or risk to the user proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED INSOLUBILITY

Up to present, those skilled in the art have avoided high doses of fiber due to side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Leitz column 1 58-63). Leitz specifically teaches that "higher in take of dietary fiber is not without risks"...and attempts to maximize the benefits of fiber at only MODEST levels of intake. (column 1 lines 55-67). Gori teaches a maximum his fiber packets are 0.5-5 grams but preferably 3.3 grams (includes the weight of the minerals).

Applicant, a board certified internal medicine physician has communicated with numerous patients, and buyers of his invention who take more than 17 grams of fiber per day, without significant side effects or any evidence of nutrient or mineral deficiency. Up to now, Leitz, Gori,

and others skilled in the art felt high dose fiber necessitated mineral and nutrient supplementation. Applicant's invention with novel physical structure has solved this problem and removed the necessity for nutrient and mineral supplementation.

Applicant's invention's ability to deliver higher doses of dietary fiber (7 grams or greater of fiber per serving) safely and without danger or risk proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

Leitz teaches that soluble fiber is associated with a reduction in LDL and serum cholesterol as well as improved glucose in the short term. (column1 lines 52-55) Leitz teaches that higher doses of fiber MAY aid in weight reduction. (column 56-58.) Nowhere in Leitz patent does he teach HIS invention reduces cholesterol or aids in weight reduction. One must assume he does not aid weight reduction as he states higher dosages of fiber are needed and he only provides modest fiber. (Column 1 lines 55-67). Leitz provides no method, means, or proof that his composition improves cholesterol or offers weight reduction. With Leitz composition these 2 benefits are unworkable. Gori teaches weight control **not** dramatic weight loss and **REQUIRES eating a proper diet—reducing fats, sugars, and calories**. There is no proof Gori's formula is anything more than a placebo, as the weight control may come entirely from reducing fat, sugar and calories, not the fiber powder sprinkled on the food. Applicant provides dramatic weight loss and cholesterol benefit showing his novel structure has overcome unworkability.

Applicant's invention with novel physical structure allows delivery of at least 7 grams of fiber per serving, safely, and without risk or danger to the user. Applicant also provides dramatic weight loss and cardiovascular risk reduction/ cholesterol benefits for the user. Applicant provides a solution to obesity, dyslipidemia , and the dangers of high fiber consumption proving that applicant's novel structure is unobvious over Leitz under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF ELEMENT(S)

Leitz's invention requires fibers from 3 different groups to provide a balanced fiber adjunct to the diet modeled after the basic food group to sound nutrition. (column 2 lines 43-45) Leitz recommends 9 fibers with at least 30% from the fruit and vegetable group, 30% minimum from the cereal group, and 3-40% from the non-fruit, non-vegetable and non-cereal group. (column 1, table 1). His fiber invention is further associated with non-toxic, inert carriers. (column 4 lines 46-49). Leitz by detailed description requires 9 different specific fibers. Leitz by claim 1 states at least 1 fiber from the fruit and vegetable group consisting of lemon, acerola, and carrot, at least one from the cereal group consisting of corn, oat and barley bran, at least one from the other (non-vegetable/fruit, non-cereal) group consisting of soybean bran, psyllium seed husk, and guar gum. Gori requires all dietary fibers known to generate specific health benefits (column 3 lines 23-25) and all the significant dietary fiber components that should be present in a well-balanced diet. (column 3 line 27-30). Gori requires 7 fibers. Gori requires at least oat and wheat fibers and minerals including manganese, selenium, zinc, copper, iron, calcium and magnesium.

Applicant's invention omits many elements. Applicant's invention does not need balanced, fruit and vegetable fibers, nor does it need 3 fibers from each group that Leitz teaches in his detailed description. Applicant does not need any of the fruit or vegetable fibers. Applicant does not require specific ratios. Applicant's invention does not need inert carriers. Applicant does not need wheat fibers or all dietary components that produce significant health benefits. Applicant does not require minerals. Whereas Leitz and Gori teach a complicated formula (Leitz column 1 table 1, and Gori column 4 fiber formula table), applicant teaches a much simpler formula that omits many elements of Leitz and Gori

Applicant's invention's omission of several of Leitz's elements proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS

See attached Declaration Under Rule 132.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS IN A FIELD THAT IS A CROWDED ART

The benefits of fiber are well accepted. Fiber supplements are a crowded field, therefore any step forward however small should be regarded as significant. Leitz does not provide information that his balanced fiber composition improves cholesterol or reduces weight. He does not provide a method, means, or specific information that his composition offers any benefit of weight reduction or cholesterol improvement. Applicant acknowledges he does mention general benefits of soluble fiber in lowering LDL lipoprotein and serum cholesterol, but one cannot assume that his composition, with his specific fibers, and specific gram amounts would provide these benefits. Gori teaches a weight control formulation but REQUIRES adopting a proper diet with reduced fats, sugars, and calories. Gori reports the general information that pectins, oat and gums can lower cholesterol. There is no proof, method, or information that his formulation lowers cholesterol and he does not claim it. While gums, pectin an oat can lower cholesterol, there is no proof that his formulation with his combination or gram weight of fibers produces this benefit. Even the best fiber regimen that researchers could postulate only offered a 5% reduction of LDL cholesterol (NCEP ATP III 2001 V20-21).

Applicant's invention as listed in claim 24 provides several steps forward over Leitz and Gori. Applicant's invention provides dramatic weight loss and cardiovascular risk reduction, as well as dramatic improvement in cholesterol, lipids, triglycerides, high sensitivity C-reactive protein, homocysteine, glucose metabolism, digestive diseases, metabolic syndrome, and provides a number of other health benefits.

Applicant can make a liquid beverage with at least 7 grams per serving. Leitz can make a beverage with 2 grams per serving. Gori does not teach a beverage with his formulation.

Applicant's beverage delivers more fiber without immediate gelling, and can be made as a zero calorie beverage. Leitz teaches a beverage made with milk or orange juice, both contain calories.

Applicant's invention's numerous health benefits provided over Leitz and Gori and can be provided in a beverage form, proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND OFFERS AN UNAPPRECIATED ADVANTAGE

Applicant's invention according to claim 24 offers several unappreciated advantages. Leitz teaches to only provide a modest dietary fiber level, as higher levels are associated with risks and nutrient depletion. Gori also teaches a balanced fiber formula that is modest in fiber level and does not exceed 5 grams per serving.

Applicant's invention provides an ultra- high level of dietary fiber (7 or more grams per serving). This along with the novel structure, provides many unappreciated advantages including weight loss without food avoidance or exercise, dramatic improvement in LDL, HDL, triglycerides, lipoproteins, and high sensitivity C-reactive protein. Leitz, Gori, and others skilled in the art, could not have anticipated the dramatic weight loss, lipid benefits and other health advantages such as lowering of high sensitivity C-reactive protein. NCEP ATP III guidelines teach that soluble fiber at 5-10 grams per day provides only a 5 % reduction in LDL cholesterol. There would be no reason to expect up to 60% reductions in LDL could occur with applicant's supplement. These guidelines also teach that HDL is usually lowered. Applicant's invention typically raises HDL and has even resulted in up to a 22 point rise. (Each HDL point increase is equivalent to a 3-4% risk reduction in cardiovascular disease). These dramatic benefits could not have been anticipated.

Applicant's invention's numerous unappreciated advantages provided over Leitz's and Gori's fiber composition proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND HAS NOT BEEN IMPLEMENTED

Applicant's invention is novel and unobvious. If the invention were obvious, if the advantages were obvious, Leitz, Gori, and those skilled in the art would have surely developed it by now. The fact that Leitz, Gori, and those skilled in the art have never created applicant's invention indicates it is not obvious.

The fact that applicant's invention was not previously created proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND QUOTED REFERENCE IS MISUNDERSTOOD

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art. Applicant believes new claim 24 further shows that invention is unobvious and that Leitz and Gori as a reference do not apply to applicant's invention.

Leitz is concerned with providing a fiber supplement that includes a balance of fiber sources from the main food groups that is to be used as an adjunct to a diet. (Column 2 lines 37-42) Leitz does not teach how his invention improves cholesterol or how it can be used for weight reduction. He only mentions in general that soluble fiber can lower LDL and serum cholesterol. Leitz specifically teaches only a modest dietary level of fiber and specifies the range of 0.5 -5

grams, **preferably 1-3 grams**, and in beverage form he teaches **approximately 2 grams per unit for administration [serving]**. (Column 5 lines 40-64).

Gori is also concerned with providing a balanced fiber formula, containing all fiber constituents that can produce health benefits. By detailed description Gori requires oat, wheat, and corn bran. He requires minerals to be added. Gori serving packets are up to 5 grams but he prefers 3.3 grams. Gori teaches a powder that must be sprinkled on foodstuffs 10 times per day.

Both Gori and Leitz are concerned with a balanced fiber formulation that contains all fiber components that can aid health. This by their teaching requires numerous fibers and Leitz demands acerola, carrot, or lemon of which one or more must account for 30-48.5% of the total fiber weight.

Applicant's invention is novel and unobvious and is not similar to Leitz or Gori . Applicant's invention is an **ultra-high fiber formulation delivering 7 or more grams of fiber per serving**. Leitz and Gori do not deliver more than 5 grams per serving and typically is much less, 1-3 grams. Applicant's fiber powder can be made into a beverage, pudding or solid. The beverage is unique in that it does not immediately gel and can even be made into a **zero** calorie liquid drink. Applicant has no interest in providing a fiber balance or a fiber composition modeled after the basic food groups. Applicant does not require a fruit or vegetable fiber and certainly does not require it to make up 30-48.5% of the formulation. Applicant does not require wheat or barley fiber.

Applicant's physical structure is very different from Leitz's and Gori's. Their uses are different as well. Leitz wants to provide a balanced fiber composition, modeled after the basic food groups as an adjunct to the diet, in modest fiber intake to avoid any risk to the user. Gori wants to provide a balanced fiber formula that provides minerals sequestered by fibers, and to make a weight control product that is conveniently added to foodstuffs. Applicant wants to deliver ultra-

high fiber (7 gram or greater per serving) safely in one or more doses daily and to optimize weight loss, cardiovascular risk reduction and a variety of other health benefits.

Applicant respectfully feels that Leitz and Gori as references were misunderstood in respect to applicant's invention. Applicant believes that claim 1 rewritten as claim 24 to more clearly show the novel structure proves the applicant's novel structure is unobvious over Leitz and Gori under Sec. 103

Applicant respectfully notes that office action in first paragraph states that Gori provides powdered forms of 0.5-5 grams and an average person may take up to ten doses per day. A ten gram fiber formulation contains 3g +/-15% oat, 2g +/-15% guar, and 1 gram +/-15% psyllium. **Office action failed to note:**

- a) Gori's formula **MUST** include wheat and corn bran, pectin, and cutins, not just the guar, oat and psyllium. Gori specifically describes his formula as a **balanced formula** requiring all these fibers!
- b) Gori's formula **MUST** include manganese, selenium zinc, copper, iron calcium and magnesium. Gori teaches the importance of the supplemental minerals.
- c) Office action failed to note that Gori is a powder that is sprinkled on food, and applicant is a beverage, pudding or solid that is taken typically 30-60 minutes before a meal, or instead of a meal.
- d) Office action failed to mention that Gori's weight control formula requires a proper diet that requires reduction in fats, sugars and calories.
- e) Office action failed to note that Gori requires foodstuffs to effect weight control, where as applicant uses fiber **WITHOUT** food to create satiety
- f) Office action failed to recognize that Gori's **largest** serving of fiber is 5 grams, applicant's **minimum** serving is 7 grams. Gori's realistic serving is 1-3.3 grams as evidenced by (column 3 lines 52-56 and column 4 lines 64-67).

In second paragraph on page 8 of office action it states it would have been obvious to provide a fibrous composition containing the recommended 25-40 grams of fiber per day with a composition by Gori in which 35 grams/day would comprise 10.5 g oat, 7 g guar, and 3.5 g psyllium.

Applicant respectfully submits this comparison has nothing to do with applicant's invention for the following reasons:

- a) Gori's proposed formula is a balanced formula absolutely requiring multiple fibers left out of this example. Gori's formula details how bran fibers are different and oat, corn, and wheat are necessary as well as the cutins and pectins. Not just the guar, oat and psyllium. Gori also requires minerals, applicant does not. How is it obvious **TO NOT use the formula he teaches**? How can one "obviously" know which fibers to include in a hybrid formula and which ones to leave out?
- b) Even if examiner's example was used, the 35 grams would be divided among 10 daily packets or servings, which then means the total gram weight is 3.5 grams and the oat is 1.05 grams, the guar 0.7 grams, and the psyllium would be 0.35 grams per serving. Applicant serves a minimum of 7 grams per serving and a minimum of 1 gram of oat, 1 gram of guar, and 0.5 g of psyllium. Even with the +/- 15% the guar and psyllium do not overlap and the serving size still is far less than applicant's 7 grams.
- c) How is it obvious to combine two independent patents ? How is it obvious to know that the only thing to combine from Leitz is the information that experts recommend 25-40 grams of fiber? How is it obvious not to use the balanced formula that Leitz teaches with the ratios of fruit and vegetable fibers, cereal fibers, and other fibers?
- d) Each reference is an independent patent and there is no suggestion or implication they can be combined. If they are combined, they both have numerous requirements that would have to all be combined in order to be put together. It would not be obvious on which parts to leave in and which parts to take out.

Applicant submits that Leitz and Gori as references were misunderstood and that applicant's novel structure is unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS CONTRARIAN INVENTION OVER PRIOR ART

Leitz teaches to make a **balanced** fiber supplement that is **only modest in the amount of fiber** per serving. Leitz teaches 0.5-5 grams could be used per unit dose serving but prefers 1-3 grams (column 5 lines 60-61). Leitz teaches it is necessary to model the fiber composition after the basic food groups and requires fibers in **specific percentages** in each of 3 groups he specifies as fibers from fruits and vegetables, cereal, and non-fruit-vegetable-cereal group. Leitz prefers 9 fibers in his invention. It is important to note that Leitz teaches away from a high level of dietary fiber as he is concerned it is dangerous and provides serious risk to the organism (column 2 lines 32-36).

Gori's weight control formulation **contains all** the significant dietary fiber components that should be present in a well-balanced natural diet. The substance of the invention is a scientifically balanced formulation of **essential natural fibers supplemented with the major minerals** that the use of such fibers requires. Gori's invention is designed to **restore the natural fiber that modern food technology is known to remove** from the processed foods which are consumed. Unlike other known products, the Gori's invention is designed to **provide all fiber varieties known to generate specific health effects** deriving from regular fiber intake. He teaches **fibers are not to be considered equal to one another**. Gori's invention is a "food additive" that must be sprinkled on each meal of the day—suggested use is up to 10 packets per day for an average 150 lb individual and proportionally more or less based on body weight. Gori teaches to make a dry powder that is **sprinkled** on food and **contains 0.5-5 grams of fiber and mineral** supplements. Gori further teaches his invention with examples of **2.0 -3.3 grams per serving**. **Gori's invention must be sprinkled on foodstuff prior to ingesting it.**

GORI teaches:

The fiber containing materials must contain **at least oat and wheat bran** (by claim). Gori's actual fiber formulation (column 4) teaches oat, wheat, and corn bran (all 3) are necessary. Gori teaches that the bran fibers are different and that the wheat is necessary as it supplies lignin, and corn is necessary as it supplies hemi-cellulose to the formulation. Gori teaches oat bran does not supply sufficient lignin or pectin to be employed by itself in the formulation, and wheat bran is essential. The formulation contains the **major minerals supplements** that use of essential natural fibers requires.

Applicant has no interest in providing balanced fibers. Applicant is only concerned with delivering ultra-high dose fiber, at least 7 grams of fiber per serving. **Applicant's invention's physical structure is contrarian to what Leitz and Gori teach.** Leitz and Gori **maximum** is 5 grams of fiber per serving, applicant's **minimum** is 7 grams. This is mutually exclusive and obviously different. Leitz requires 30-48.5% of the fiber weight to come from the fruit and vegetable fiber group, applicant requires no fruit and vegetable fibers. Gori requires oat and wheat and only makes a powder that must be **sprinkled on food**. Gori teaches you must have his minerals supplementing the formula. Applicant is concerned with optimizing health benefits especially reducing weight and cardiovascular risk factors through delivering ultra-high dose fiber (7 grams or greater per serving) one or more times daily. **Applicant does not require minerals, acerola, carrot, and lemon pulps, wheat, barley and corn brans, and supplement can be made into a liquid, semisolid (pudding), or solid.**

Applicant's invention is contrarian to what Leitz and Gori teach and therefore proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND BELIEVES LEITZ AND GORI ARE "PAPER PATENTS"

Applicant is a board certified internal medicine physician who has made other nutritional supplements and skin care products. Applicant is aware of most treatments for improving health and preventing disease, whether prescription, over the counter, or through a variety of marketing channels. Applicant is unaware of Leitz or Gori invention in the market place yet both patents being more than 10 years old. Applicant respectfully believes neither is currently being made or sold and is in fact 'paper patents'. Applicant believes Leitz and Gori were never implemented or commercialized and therefore should be construed narrowly. Applicant respectfully also feels Leitz should be construed narrowly as Leitz teaches the necessity of a variety of different fibers to make a balanced fiber composition, then claims in claim 1 as few as 1 fiber from each of three groups. (column 3 lines 40-47) **Either his balanced fiber composition requires a "good variety or range of types of fiber" or it doesn't. Leitz description absolutely requires 9 fibers as evidenced by a minimum individual range of 1% for each, his claim 1 indicates his composition could be made with as few as 3 fibers. Applicant finds Leitz description of his invention to contradict his claim 1. (column 3 lines 44-47.)** Applicant sees several problems with Leitz's invention. Leitz teaches the bulk powder can be mixed with milk or orange juice or that it can be sprinkled on salad or breakfast food. (column 5 lines 41-46). Applicant notes that any food item including milk and orange juice contain calories and using 2 grams [Leitz's recommended dosage] of bulk powder 1-4 times per day [with orange juice or milk] could result in a significant calorie load, resulting in weight gain, and all the resulting health problems that accompany weight gain. (column 5 lines 40-63). Leitz prefers a tablet as the delivery form. In regard to the tablet, it appears he would put 1-3 grams per serving. (column 5 lines 46-63). Applicant raises potential problems swallowing the size of the tablet that would be necessary to hold 1-3 grams of fiber, and the potential danger of the tablet being swallowed and sticking in the lower esophageal sphincter, and the ability of the compressed tablet to even disintegrate in the stomach (a compressed tablet of fiber would require high compression to hold the tablet together and it may not disintegrate in the stomach due to this high compression. Leitz teaches a chew tablet could be made. Applicant respectfully suspects a chew tablet would likely gel in the mouth and be unpalatable if it contained 1-3 grams of fiber and was designed to be chewed for a brief period of time. (column 6 lines 3-9). Applicant also believes Gori's invention has

some problems. As a physician, applicant is aware that compliance decreases with increasing number of times a medication needs to be taken. Gori requires 10 or more packets per day. It is highly unlikely individuals consuming his product could stay on a 10 or more pack regimen per day. Gori also recommends that at least 10 grams per day given as 10 packets per day (column 4 lines 64-68) yet claims packets containing 3.3 grams per packet, ten packets per day both for the same 150 lb average individual. If the person weighs more they have to take more packets. There is no evidence that the fiber product he describes would not be inconvenient or **ruin the taste of the foodstuffs it is being added to. Pectin is known to have a bitter taste and difficult to hide, yet it is 10% of his formula. To the contrary, applicant's invention is convenient to take and is sold commercially and is commercially successful.**

Applicant respectfully believes Leitz and Gori are paper patents where as applicant's invention is commercially successful. Therefore, Leitz and Gori should be construed narrowly and this proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND NO CONVINCING REASONING IS PROVIDED

Claim 1 has been rewritten as new claim 24 to more particularly define the invention in a patentable manner over the cited art. Applicant believes new claim 24 further shows that the novel physical structure is unobvious and that Leitz and Gori as a reference do not apply to applicant's invention and that no convincing reasoning exists as to the obviousness of applicant's invention.

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the multiple differences noted over the prior art, would have been obvious thus proving that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 & 45 ARE UNOBVIOUS UNDER SEC. 103

Claim 16 was rejected under 35 U.S.C 103(a) as being unpatentable over the combination of Leitz (US patent 4,877,627) and Gori (US patent 4,784,861).

Claim 16 was cancelled and rewritten as new claims 42 and 45 to more particularly define the invention in a patentable manner over the cited prior art.

CLAIM 42 recites a method of administering at least 7 grams of fiber to a mammal, comprising guar, oat and psyllium (specific fibers with special physical properties) and at least one flavoring agent, admixed with an edible liquid selected from the group of zero calorie and calorie containing liquids to create at least an 8 ounce beverage selected from the group of zero calorie and calorie containing beverages administered once or more daily.

This novel structure comprising 3 specific fibers with specific physical properties and at least one flavoring agent and containing a minimum of **7 grams** of fiber per serving, can be admixed with a liquid to create a beverage that does not immediately gel. Admixing a zero calorie liquid such as water, creates a zero calorie beverage. Applicant's drink can be made with as few as 3 fibers which are guar, oat, and psyllium.

Gori does not teach to make a beverage. Leitz teaches a beverage that is approximately 2 grams of fiber and must be admixed with a liquid food product such as orange juice and milk to aid administration. (column 5 lines 41-46). Leitz drink must still meet all his requirements of the multiple different fibers, each of 3 groups, and each with specific percentages and typically contains inert non-toxic carriers. Applicant does NOT require binders, inert carriers, or lubricants. **Gori and Leitz to do not provide any method claims.**

CLAIM 45 recites a method of administering at least 7 grams of fiber to a mammal, comprising guar, oat and psyllium (specific fibers with special physical properties) and at least one flavoring agent, to which at least one ingredient is admixed to create an edible food product selected from the group consisting of puddings, snack bars, wafers, and dog bones. As part of the method at **least one liquid has to be consumed with the edible food product to hydrate the consumed fiber.** Gori does not mention consuming his product with a liquid. Leitz briefly discusses that his chewable tablet can be swallowed with liquid, this is to help swallow his chew tablet, not to hydrate the fiber. (Column 6 lines 4-9) Applicant questions whether any individual could tolerate chewing a fiber tablet containing 1-3 grams of fiber no matter what flavoring agents have been added.

This novel structure has a minimum of **7 grams** of fiber, admixed with a an ingredient to make a edible food product selected from the group consisting of puddings, snack bars, wafers, and dog bones is novel. **Gori and Leitz do not teach to make more than 7 grams of fiber per serving and neither teaches to make a pudding, snack bar, wafer or dog bone. Neither teaches to consume an additional liquid with the fiber product to hydrate the consumed fiber.**

Applicant's edible food product could be made only with guar, oat, psyllium and a flavoring agent and Gori and Leitz cannot.

LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR COMBINATION, MUCH LESS THE MANNER PROPOSED

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior- art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.... *Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary

skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness Only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently.** Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches

dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant's because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

"That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention."

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P.

706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra, a “factual basis to support his conclusion that it would have been obvious” to make the combination.

Applicant argues that Leitz and Gori cannot be combined. They are both independent patents that do not suggest they can be combined, they are both references that are individually complete, they teach away from a suggested combination, and they cannot be combined based on their requirements. **Importantly Gori uses the term “consisting of” in describing his main claim which teaches his formulation is closed ended and CANNOT be combined. Leitz uses the term open-ended term “comprising of” to describe his main claim and that indicates that his composition must include AT LEAST his requirements.** Many of the requirements of Leitz and Gori are mutually exclusive and even though applicant submits they cannot be combined, but even if they were combined, how can it be obvious to know what to combine? Gori teaches oat, corn, and **wheat** are a necessity, Leitz does not teach wheat but instead oat, corn and **barley** bran. Even if all the different fibers are added there would be at least 12 different fibers and there could be potential interactions with the fibers, which would increase clumping or gelling, or make it difficult to sprinkle on food. **Leitz requires 30-48.5% of fiber to come from the fruit and vegetable group, Gori teaches at most 15%.** Gori teaches 14.6% (column 9 table showing fiber content in grams in formulation of cutin and pectin $= 3.0 + 1.9 / 33.4 = 14.6\%$ and % of fruit and vegetable group in column 10 table is $10 + 15 / 100 = 15\%$ fiber from the fruit and vegetable group. **If Gori teaches 15% and Leitz 30-48.5% of fiber must come from the fruit and vegetable group then they teach mutually exclusive information.** How can combining mutually exclusive information be obvious?

Applicant stresses both references **teach away from high fiber** and though offer their fiber formulation in up to 5 grams per serving, realistically teach 3-3.3 grams maximum fiber per serving (Leitz 1-3 grams and Gori 1-3.3 grams which includes mineral weight). Applicant wishes to note that the 0.5-5 gram per packet for Gori is his entire formulation of which includes his mineral supplements, the fiber component would be somewhat less.

The following combination of Leitz and Gori would have to contain at least the following based on the two patents:

1. a maximum of 5 grams of fiber per serving
2. at least oat, corn, barley, and wheat brans
3. the cereal component would have to make up 30-48.5% of the final fiber weight,
4. (Leitz) 30-48.5% fiber from the fruit and vegetable group vs. maximum of 15% (Gori)
5. lemon, acerola, and carrot pulp
6. 3-40% of the other fibers not from fruit, vegetables, or cereals
7. mineral supplements manganese, selenium, zinc, copper, iron and calcium
8. Must be administered throughout the day sprinkled on foodstuffs.
9. Served as a powder, tablet, chewable tablet, granules, or bulk powder. (A 2 gram fiber per serving beverage requiring liquid food product to ease administration is described by Leitz but not claimed)

Applicant

- a) Minimum of 7 grams of fiber per serving
- b) At least oat, guar, and psyllium and does not require any other fibers
- c) No mineral or nutrient replacement requirements
- d) Taken in one or more doses typically 30-60 min before food or instead of food, not with food.
- e) Preferred is a drink, but could be served in a pudding snack bar, wafer or dog bone

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar,

a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant submits the novel features of claims 42 and 45 are unobvious under Leitz and Gori for a variety of reasons.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS DUE TO ENORMOUS DIFFERENCES IN PHYSICAL STRUCTURE

As noted above applicant provides a method claim to teach how to deliver a minimum of 7 grams of fiber to a mammal safely and without the need for nutrient or mineral replacement. Leitz and Gori teach away from high fiber due to the dangers and teach a maximum of 5 grams per serving, but prefer much less (1-3.3) grams.

Applicant provides a method to create a liquid, semi-solid and solid comestible, more specifically a beverage, pudding, snack bar, wafer and dog bone. Leitz and Gori do not teach the pudding, snack bar, wafer and dog bone. Gori does not teach a beverage. Leitz teaches a balance fiber beverage containing 9 different fibers yet results in only approximately 2 grams of fiber delivered per serving and it is admixed with a liquid food product to aid administration. Furthermore, Leitz typically has inert non-toxic carriers associated with it. Applicant serves a minimum of 7 grams of fiber per serving, does not require inert carriers, and does not need liquid food products to aid administration. Furthermore applicant creates a zero calorie beverage with as few as 3 fibers.

Applicant stresses that Leitz and Gori teach dangers of high fiber and teach a maximum of 5 grams of fiber per serving, but realistically and preferably teach only 1-3 grams per serving. **It cannot be obvious to look at Leitz and Gori and then create an invention with a MINIMUM of 7 grams of fiber per serving.**

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant submits that the novel physical structure of claims 42 and 45 are not taught by Leitz and Gori and proves applicant's novel structure is unobvious over the combination of Leitz and Gori.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS DUE TO UNEXPECTED RESULTS

Applicant's method claim teaches how to deliver ultra-high fiber (at least 7 grams per serving) to a mammal. The composition of that fiber supplement (same as claim 24) has novel physical features using three specific fibers that can be used to make a beverage that does not immediately gel, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. In the preferred embodiment a zero calorie beverage is created that delivers a minimum of 7 grams of fiber per serving. This has resulted in new and unexpected results. Applicant's invention results in dramatic safe, easy weight loss, removes the need to avoid foods or exercise, allows for snacking with a zero calorie beverage, avoids yo-yo dieting, dramatically improves cholesterol results to the point individuals can reduce or even eliminate their cholesterol medications, gives dramatic improvement in high sensitivity C-reactive protein, gives dramatic improvement of the metabolic syndrome and dramatically reduces cardiovascular risk.

Leitz's and Gori's inventions have different physical structures, Leitz containing 9 fibers and Gori 7. As Gori teaches **"Fibers are not considered to be equal to one another"** (Column 3

lines 25-26). Neither teaches dramatic weight loss. Both comment that it is generally accepted that fiber lowers LDL cholesterol. **Neither teaches that their invention does specifically affect lipids and the implication should not be made.** Not all food stuffs containing soluble fiber will actually lower LDL and serum cholesterol. You need the correct minimum gram weight of certain fibers to lower cholesterol. There is no proof that Leitz which contains 0.8 grams of guar, oat, and psyllium per maximum 5 gram of fiber serving, and Gori which contains much less than 1 gram of these same fibers would provide any cholesterol lowering. **Furthermore, neither teaches their invention actually reduces cardiovascular risk.**

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's dramatic health benefits are very important, valuable and unexpected which clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS DUE TO ASSUMED UNWORKABILITY

Up to present time those skilled in the art have not produced a liquid beverage, pudding, snack bar, wafer or dog bone that contains a minimum of 7 grams of fiber per serving and could be made with as few as 3 specific fibers. In regard to beverages, combining fibers in high dose results in immediate gelling. No commercial beverage is available containing a minimum of 7 grams of fiber as no one skilled in the art has found a way to put so much fiber in a unit dose without having it immediately gel. Applicant's invention using specific fibers with

characteristics and specifications described allows applicant's invention to contain a minimum of 7 grams of fiber per serving and to be consumed as a liquid beverage without immediate gelling. Applicant's invention does not require inert carriers, minerals, supplements or excipients to prevent gelling.

Up to present time, those skilled in the art have not produced a zero calorie beverage that causes satiety. Applicant's invention using specific fibers with specific physical characteristics as described in the original specification allows applicant's invention to contain a minimum of 7 grams of fiber per serving and have **zero calories** per serving. Applicant's invention induces satiety. Leitz does not teach weight loss, Gori teaches weight control by sprinkling his fiber formula on foodstuffs throughout the day. **Gori still requires a diet low in calories, sugar, and fats to aid in weight control.** Applicant's weight loss occurs by a different mechanism than Gori. **Applicant creates satiety by delivering ultra-high fiber (at least 7 grams per serving) 30-60 minutes before the meal, and can be taken once per day. Gori must consume his fiber with foodstuffs throughout the day, and does not cause satiety.**

Applicant's invention allows for compliance in consuming ultra high doses of fiber. It is pleasant tasting and more than 14 grams of fiber can be consumed in two 8-20 ounce beverages. In the preferred alternate embodiment 1A, 17 grams of fiber is delivered in two 8-20 ounce beverages before one meal.

Leitz and Gori use different fibers and require a balance of fibers, which necessitates using 7-9 fibers. Combined, Leitz and Gori require a minimum of 12 different fibers. Gori also requires minerals to be added to the invention. Leitz can make a liquid fiber supplement but it requires an inert carrier.

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a

beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention overcomes prior arts inability to deliver ultra high doses of fiber per serving. Leitz and Gori actually teach against serving high levels of fiber per serving.. Applicant's method of weight loss and physical structure does not resemble Gori's weight control formula so therefore, could not have been obvious. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS DUE TO ASSUMED INSOLUBILITY

Up to present, those skilled in the art have avoided high doses of fiber due to gastrointestinal side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Leitz column 1 lines 58-63). **Gori's balanced fiber supplement necessitates the addition of "major minerals"**. (Gori column 3 line 19-22)

Applicant, a board certified internal medicine physician has communicated with numerous patients, and buyers of his invention who take **more than 14-28 grams** of fiber per day, **without significant side effects or any evidence of nutrient deficiency**.

Up to present, virtually all diets require avoidance of certain foods, or an increase in exercise. Many contain dangerous stimulants. These are necessary requirements for people to lose weight. Most people cannot indefinitely avoid foods they crave, or keep committed to a daily exercise program. This results in dangerous weight swings or yo-yo dieting. Applicant's invention induces satiety prior to the meal with a zero calorie beverage that avoids the use of dangerous stimulants. No food avoidance or exercise is necessary to lose weight. People using applicant's invention, find it easy to take the beverage, eat the foods they enjoy (albeit less of them due to

the satiety) and lose weight. Some have commented they have tried several diets and this is the first one that has worked. Because no food avoidance or exercise is needed, people easily continue on the beverage until ideal body weight is achieved. Yo-yo dieting is prevented.

Leitz does not teach that his invention can even promote **weight loss**. **Gori's weight control formulation does not teach dramatic weight loss and requires, "...it is essential to adopt a proper diet, to reduce fats, sugars and calories in general..."** (Column 4 lines 10-12)

Applicant respectfully questions whether the avoidance of fats, sugars, or calories produces "weight control" or whether it is Gori's invention itself.

Applicant's invention produces dramatic weight loss without food avoidance or exercise, or the use of dangerous stimulants. Applicant produces satiety by different mechanisms including inducing satiety that is not part of Leitz or Gori. (Leitz teaches that high intake of dietary fiber can aid weight loss, but teaches against high intake of fiber due to its dangers.) Applicant's invention avoids yo-yo dieting. Applicant's invention allows a subject to consume more than 7 grams of fiber per serving without significant side effects or the need for mineral supplementation. Applicant's invention overcomes these problems due to novel physical structure and the use of specific fibers with specific characteristics and specifications.

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant has found a way to deliver ultra-high fiber (at least 7 grams per serving) safely and without the need for nutrient or mineral supplementation and clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

**THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS
BECAUSE IT IS A COMMERCIAL SUCCESS**

See Declaration Under Rule 132.

Applicant respectfully believes Leitz's and Gori's inventions are "paper patents" that have not been made commercially. Applicant's invention is commercially successful due to applicant's novel physical structure and the dramatic health benefits it produces.

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's novel structure and resulting benefits has allowed applicant to be commercially successful by word of mouth advertising and little or no formal advertising. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

**THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS DUE
TO PROGRESS IN CROWDED ART**

Weight loss products and products that profess to lower cholesterol are a significant portion of the multi-billion dollar nutritional supplement and prescription drug industry. This is a very crowded art. Applicant's invention with novel physical features produces new and unexpected results including, safe, easy weight loss - many times dramatic weight loss, without the need for

food avoidance, exercise, prescription drugs or dangerous stimulants. Applicant's invention avoids yo-yo dieting, and produces **dramatic** reductions in cholesterol, triglycerides, lipoproteins, and high sensitivity C reactive protein. Each of these novel steps should be regarded as significant.

Leitz and Gori do not teach dramatic weight loss, but instead teach a balanced fiber supplement. Leitz does not teach weight loss, rather a balanced fiber supplement to be used as an adjunct to the diet. . **Gori's weight control formulation does not teach dramatic weight loss and requires, "...it is essential to adopt a proper diet, to reduce fats, sugars and calories in general..."** (Column 4 lines 10-12) Applicant respectfully questions whether the avoidance of fats, sugars, or calories produces "weight control" or whether it is Gori's invention itself. **Leitz and Gori do not teach that their inventions give cardiovascular risk reduction. Even if Leitz and Gori could lower LDL by 5% as the best studies of soluble fiber show, that would not produce a significant reduction in cardiovascular disease for most people.**

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention has novel physical structure over Leitz and Gori and produces numerous advantages including safe, easy and many times dramatic weight loss, as well as dramatic reduction in cardiovascular risk. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS DUE TO OMISSION OF AN ELEMENT(S)

Applicant's invention contains **as few as 3 fibers** (guar, oat, and psyllium) each having specific physical structure, characteristics and behaviors. Applicant's invention is a minimum of 7 grams of fiber per unit of administration. **Leitz's invention contains 9 fibers and requires a non-toxic inert carrier to make it liquid.** (Column 4 lines 45-52). Leitz requires a complicated fiber formulation modeled after the basic food groups and balanced after the basic food groups (Column 2 lines 37-47). Leitz requires acerola, carrot and lemon pulp, as well as soy bran, barley bran and other fibers. **Gori's invention contains 7 different fibers** with attention to 3 types of bran (oat, wheat, corn) (table Fiber Formula column 4) and though he discusses the necessity of each of the three types of bran he claims at least **2 brans -oat and wheat brans (claim 1).** **Gori's invention requires minerals to be added as well. Gori's invention is a food additive sprinkled on all meals.**

Applicant's invention can use as few as three fibers, does not require fruit or vegetable fibers or two types of bran, nor inert carriers to make it liquid, nor does it require consumption of food, or supplemental minerals. Applicant's invention delivers a minimum of 7 grams of fiber per serving one or more times daily. Typically patients take 1 serving (based on 2 scoops per serving) which provides a **minimum of 14 grams of fiber (actually 17 grams) in two doses.** Leitz and Gori, require multiple doses based on their preferred unit dose administration of 1-3 grams for Leitz (2 grams in bulk powder form) (column 5 lines 40-43) and Gori's preferred 1-3.3 grams (includes non fiber weight components) and is taken 10 times per day (column 3 lines 53-56) . **Applicant believes that limiting the number of times the fiber must be consumed is a significant advantage and improves compliance.**

Applicant's invention is much simpler, cleaner, and easier to use than Leitz and Gori. Applicant's invention does not require a balance, but instead uses fibers with certain physical structure, characteristics, and behaviors. **Applicant omits the need for a variety of fibers, the need for minerals, the need for a balanced fiber formulation, and the need for specific fibers such as wheat, acerola, carrot, soy bran, barley bran and lemon.**

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention novel physical structure and omission of elements clearly proves it is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 DUE TO UNSUGGESTED MODIFICATION

Leitz and Gori lack any suggestion that either reference should be modified in a manner to meet claims 42 and 45. Leitz and Gori both teach their invention could be given in a 0.5-5 gram dose. Although Leitz uses the term "about 5 grams", applicant submits that this should not be interpreted to mean more than 5.49 grams as anything higher would round up to 6 grams, and if Leitz wanted 6 grams he would have stated "about 6 grams". It would not be logical to round up for Leitz anyway, as Leitz prefers to provide servings with much less fiber in them.. Leitz actually prefers 1-3 grams, and 2 grams if it is liquid. It appears that Gori's gram weight maximum of 5 grams includes the weight of minerals and other excipients. Gori doesn't really intend to use 5 grams per serving instead he prefers 1-3.3 grams per serving. Neither reference teaches to make a fiber supplement that is more than 5 grams. **Leitz specifically teaches against a high fiber level intake, preferring to provide the benefits of fiber at a modest dose. Gori teaches to add the invention throughout the day to all meals** spreading the total grams of fiber (10 grams/day) over multiple meals. (column 3 lines 47-52)

Claims 42 and 45 teach that applicant's supplement can be administered as a drink, zero calorie drink, pudding, snack bar, wafer or dog bone. Leitz teaches to make a tablet, bulk form that can be sprinkled on food, or mixed with a food product to make a 2 gram fiber drink, granules and a

chewable tablet. Gori only teaches to make a powder that is sprinkled on food. Applicant's novel physical forms of administration are different and not suggested by Leitz and Gori. Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

No suggestion is made in either reference to provide 7 grams or more of fiber per serving, and in fact, the 2 references **teach against increasing the fiber greater than 5 grams**. Leitz and Gori require numerous different fibers to create their balanced formulas, applicant does not require more than 3 fibers. Applicant's physical forms of administration are different than Leitz and Gori. Applicant's novel physical structure proves it is unobvious under Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS DUE TO UNAPPRECIATED ADVANTAGE

Up until present, those skilled in the art were unaware of the dramatic weight loss and lipid benefits from serving a minimum of 7 grams of specific fibers per serving on a daily basis. While it is generally recognized that fiber is healthy, can reduce LDL cholesterol, and could reduce some forms of cancer, the **dramatic** weight loss, and **dramatic** reductions in risk of cardiovascular disease through providing a minimum of 7 grams of fiber per serving once or more daily have been unappreciated.

Fiber is well known to lower LDL cholesterol but current belief is that consuming 5-10 grams of viscous fiber only results in a 5% reduction in LDL cholesterol. (NCEP ATP III guidelines 2001 V21). Oat and psyllium have shown reduction in HDL cholesterol (Anderson 1995) and other reviews show little, no, or inconsistent HDL results. (NCEP ATP III guidelines 2001 V21).

High sensitivity C-reactive protein is an independent risk factor for cardiovascular disease. Fiber is not a medically known treatment for high sensitivity C-reactive protein.

Applicant's invention produces an unappreciated advantage. Delivering 7 or more gram of fiber once or more daily of applicant's novel fiber supplement produces a number of unappreciated advantages. Applicant, a physician and lipid expert, has documented lipid improvements that are dramatic and have even resulted in some individuals decreasing or even eliminating their cholesterol medications. **Instead of the known 5% LDL cholesterol reduction that soluble fiber can produce, applicant's invention has dropped LDL by more than 100 points (and up to a 60% reduction). Applicant's invention has provided dramatic triglyceride and HDL improvements as well. Applicant has documented triglyceride reductions of more than 130 points or reductions of up to 82% and instead of HDL reductions, applicant's invention typically raises HDL and has even produced as much as a 22 point rise or 56% increase. Applicant's invention reduces cardiac inflammation by lowering high sensitivity C-reactive protein levels. Some of these reductions in high sensitivity C-reactive protein have been very dramatic, taking individuals at the highest risk levels down to the lowest risk levels.**

Leitz and Gori do not teach that their inventions reduce cardiovascular risk or specifically that their invention reduces LDL cholesterol, they only comment that it is generally accepted that the fiber reduces LDL cholesterol. Applicant, a medical doctor and lipid expert, submits that just because a composition contains soluble fiber, does not mean that it automatically lowers cholesterol. Very specific fibers in very specific amounts are necessary to lower cholesterol. The other ingredients and additional fibers added to a formula could actually negate the effects of good fiber on lowering cholesterol.

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar,

a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention produces unappreciated advantages over prior art. Applicant's novel physical structure produces unappreciated advantages over Leitz and Gori which clearly proves the novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS DUE TO LACK OF IMPLEMENTATION

If applicant's invention was in fact obvious, because of its advantages, those skilled in the art surely would have implemented it by now. The fact that those skilled in the art have not implemented applicant's invention despite its great advantages, indicates that it is not obvious. Prior art has used oat, guar and psyllium fibers, but no prior art has taught how to use fibers with specific characteristics and specifications so as to create a minimum of 7 grams of fiber per serving that could be easily taken in one or more daily doses and produces safe, easy and dramatic weight loss, as well as dramatic cardiovascular risk reduction.

If using 7 or more grams of fiber per serving was obvious, Leitz and Gori would have surely taught that in their patent. The fact that they taught 5 grams maximum and preferred only 1-3 grams per serving indicates applicant's invention was unobvious. While prior art has used guar, oat, and psyllium none has combined the three fibers with the specifications listed in claim 24 or the method claims 42 and 45.

The lack of implementation of the applicant's invention along with its novel physical structure clearly proves applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS DUE TO A MISUNDERSTOOD REFERENCE

Applicant respectfully believes that the references provided in the office action were misunderstood. Applicant has rewritten claim 16 as claim 42 and 45 to better define the novel physical features and add clarity to the invention.

Applicant's invention is an ultra-high fiber supplement **containing a minimum of 7 grams** of fiber per serving comprising guar, oat, and psyllium. Leitz and Gori teach a balanced fiber formulation that requires a variety of different fibers. Leitz recommends 9 fibers and Gori 7. All of these fibers are necessary as they provide the balance and novelty to the reference's inventions. Applicant's supplement is not a fiber balanced formula. Applicant is not interested in balance, just providing an ultra-high fiber (at least 7 grams per serving) with fibers that provide dramatic health benefits. Leitz and Gori do not recommend more than 5 grams per serving, and actually prefer 1-3 grams. Leitz teaches a balanced fiber composition modeled after the basic food groups to serve as an adjunct to the diet, to give benefits of fiber at a modest level of intake. Gori teaches a balanced fiber formulation that can be used for weight control by sprinkling his powder on foodstuffs throughout the day. Gori teaches weight control that requires eating a proper diet, and reducing fats, sugars and calories. Applicant teaches dramatic weight loss without food avoidance or exercise. Applicant's supplement is taken 30-60 minutes prior to food not sprinkled on food. Applicant teaches dramatic weight loss, and cardiovascular risk prevention –Leitz and Gori do not. Gori teaches mineral supplementation is necessary, Applicant does not.

Applicant provides a method of administering the novel physical structure fiber supplement in liquid, semisolid, and solid form which is different than Leitz and Gori. Leitz prefers tablet, chew tablet, bulk form for granules on food, or for a 2 gram fiber drink. Applicant provides for a beverage containing 7 grams of fiber per serving, a zero calorie beverage, a pudding, a snack bar, a wafer, and a dog bone. These are very different than Leitz and Gori's comestibles and hence, applicant is unobvious over Leitz and Gori under Sec. 103.

Applicant's nutritional supplement is an ultra-high fiber (at least 7 grams per serving) supplement that is not balanced, does not require minerals or several of the specific fibers required by Leitz and Gori, is administered in different oral forms, and provides different benefits. These references do not anticipate applicant's invention or make it obvious.

THE NOVEL PHYSICAL FEATURES OF CLAIM 42 AND 45 ARE UNOBVIOUS AS THEY PROVIDE A SOLUTION TO A LONG- FELT AND UNSOLVED NEED

Diets don't work for most people. This is why there are so many different diets, pills, programs, books, etc. Despite the plethora of diet solutions 2/3 of Americans are overweight and more than 30 % are obese.

Applicant's novel physical structure serving an ultra-high fiber (at least 7 grams per serving) and comprising 3 specific fibers with unique physical characteristics allows special advantages. Applicant's supplement delivers ultra-high fiber (at least 7 grams per serving) in an easy to take manner without danger to the mammal or the need for mineral or nutrient supplementation. Applicant's supplement can be admixed with a liquid to make an ultra-high fiber (at least 7 grams per serving) beverage that will not immediately gel. When water is used as the liquid a zero calorie beverage is created. Applicant produces dramatic weight loss in a safe and easy manner. This invention solves several long-felt and unsolved needs including how to lose weight without dieting or exercise, how to administer high dose fiber without danger, how to dramatically lower cholesterol without prescription drugs, how to lose weight and prevent gaining it back, etc.

Applicant's novel structure allows delivery of ultra-high dose fiber per serving that brings satiety prior to the meal. Individuals attempting to lose weight can eat any foods they like, they will feel full prior to eating and then will eat less. Because they eat less, they lose weight. Applicant is a practicing physician and has documented dramatic weight loss without yo-yo dieting. Users of applicant's invention state they don't feel hungry, and for many this is the first diet that has

actually worked. Applicant has documented individuals who have not regained weight even after one year of use. Some maintain ideal body weight using a lower dose of the invention, some use it only occasionally, and some state that applicant's invention has retrained them to eat smaller portions and do not require the invention any longer. The majority of the users take one serving (2 scoops each having more than 7 grams of specific fibers). The ease of use and the ability to deliver more than 14 grams of fiber in as few as two beverages per day greatly improves results and compliance.

Leitz and Gori have very different physical structures. Leitz has 9 fibers, Gori has multiple fibers (7 preferred) with minerals. Even combining them would not offer the advantages to weight loss that applicant's invention offers. Leitz is a balanced nutritional composition used as an adjunct to the diet, Gori is a "weight control substance" sprinkled on food and requiring 10 packets per day. Gori's weight control requires dieting, whereby a low fat, low sugar, and low calorie diet is required. Even if combined the physical structures are very different than applicant's and work by different methods. Applicant's invention results in dramatic sustained weight loss. Leitz's and Gori's invention at best, may help control current weight—neither teaches significant weight loss.

Another solution to a long-standing problem is "how can an individual significantly reduce risk of cardiovascular disease without taking prescription medication?" The same argument can be made for applicant's dramatic reduction of cardiovascular risk. Applicant's novel physical structure of specific fibers with specific physical characteristics results in a variety of lipid improvements as well as in high sensitivity C-reactive protein. The ability to deliver more than 7 grams of this novel fiber supplement per serving is an important discovery. The fact that more than 14 grams of fiber are delivered in as few as two doses, provides compliance and ease of use that results in dramatic cardiovascular risk reduction.

Leitz's and Gori's invention does not teach to cardiovascular risk reduction, and does not teach they actually improve serum lipids, or high sensitivity C-reactive protein, rather they teach that it

is generally accepted that fiber lowers LDL and serum cholesterol. Neither claims HDL or high sensitivity C-reactive protein level improvement that applicant does. Applicant, a medical doctor and lipid expert cautions that just because a formula contains soluble fiber does not mean it lowers cholesterol, or lowers it significantly. The type of fiber, the amount of fiber, and the other ingredients all play a role in the ability for the supplement to improve cholesterol levels.

It is clear that applicant's invention with novel physical structure provides a method of delivering ultra-high fiber (at least 7 grams per serving) of specific fibers, which provides numerous health benefits that cannot be claimed by the either Leitz or Gori, in individual or in combination. These benefits solve many long-felt and unsolved needs. These valuable results clearly prove that applicant's novel structure is unobvious over Leitz and Gori. under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS AND PRODUCES A CONTRARIAN INVENTION

Applicant's invention is novel in that it allows safe and easy administration of an ultra-high fiber (at least 7 grams per serving) supplement using as few as three specific fibers. This is totally contrarian to Leitz and Gori, which teach to use 5 grams of fiber or less per serving, and that a balanced fiber composition involving many different fibers is necessary. **Leitz and Gori teach that high fiber levels are dangerous and that is why they do not exceed 5 grams per serving. Both teach that high fiber prevents absorption of nutrients and minerals.** Gori teaches that mineral supplementation is a necessary part of his formulation.

Leitz's and Gori's inventions teach that a balanced fiber formulation is necessary and Gori makes the addition of minerals a further necessity. Leitz teaches to use balanced fiber to provide the benefits of fiber at a modest dose of fiber. Both teach that high doses of fiber are not well tolerated and dangerous. These two references whether individual or in combination teach away from giving high fiber to a mammal. As further proof of teaching away from delivering high

fiber per serving, Gori, teaches his daily fiber 10 gram dose should be delivered in 10 individual packets that are sprinkled on all foodstuffs throughout the day.

Applicant's invention is an ultra-high fiber (at least 7 grams per serving) supplement that is not balanced, and contains a **minimum** of 7 grams of fiber per serving safely to a mammal and without need for mineral or nutrient supplementation. This is totally contrarian to what Leitz and Gori teach.

Applicant has novel physical structure and teaches a supplement that differs in structure and function than Leitz and Gori. Applicant submits that the rewritten claims 42 and 45 clearly show that Leitz and Gori are not similar to applicant. Applicant's invention with novel physical structure and ultra-high fiber (at least 7 grams per serving) is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention provides **a method of delivering safe, healthy fiber with a minimum of 7 grams of fiber per serving, with as few as 3 specific fibers** one or more times daily. Fourteen grams or greater of fiber can be delivered in as few as 2 servings. Applicant's novel physical structure and ability to deliver ultra-high fiber (at least 7 grams per serving) safely without need for minerals or nutrient supplementation is valuable and clearly proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS DUE TO A NEW PRINCIPLE OF OPERATION

Applicant's invention has blazed a new trail. Applicant's novel structure shows that a variety of health benefits can not only be provided, but maximized through providing a fiber supplement **that is not balanced, does not require mineral supplementation, and can deliver a minimum of 7 grams of fiber per serving without immediately gelling.** One advantage of delivering ultra-high fiber (at least 7 grams per serving), is **that fewer doses are needed to**

deliver very high amounts of fiber daily. This results in improved compliance and new and unexpected results with respect to dramatic weight loss and cardiovascular risk reduction.

The majority of weight loss products require dangerous stimulants, food restriction, exercise, calorie counting, food substitution, etc. Applicant's dramatic weight loss is very different than Gori's weight control. Applicant does not require food avoidance or exercise to lose weight.

Gori requires a proper diet, with reduction in fats, sugars, and calories. Applicant respectfully suggests that Gori's weight control is due to dieting and not his invention.

Furthermore, Gori teaches that his weight control substance must be sprinkled on food **10 packets** per day "evenly spaced throughout the day on all foodstuffs". (column 3 lines 47-49).

Applicant respectfully notes that Gori's invention changes the flavor and consistency of all food that an individual would eat during the day as the fibers themselves have taste and organoleptic properties. Applicant, a physician does not see how any individual could be compliant with having to sprinkle fiber on all food consumed as it would alter the taste of food, making all food have the same "fiber" taste. Having to sprinkle 10 packets throughout the day is an absolute compliance nightmare. To make matters worse Gori teaches more fiber would be proportionally used for individuals of higher weights. This means that most people using his weight control diet would weigh more than 150 lbs and thereby require even more packets per day. **Combining Leitz and Gori would end up with a balanced multi fiber substance that requires mineral supplementation and would need to be taken with food 10 doses per day.** Applicant's invention has none of these requirements.

Applicant teaches weight loss by consuming the ultra-high fiber (at least 7 grams per serving) comprising 3 specific fibers once or more daily without the need for proper diet, or conscious reduction of fats, sugars, or calories. Applicant's method of weight loss is very different than Gori's and not even suggested by Gori. Leitz does not teach weight loss.

Applicant has novel physical structure and teaches a supplement that differs in structure and function than Leitz and Gori. Applicant submits that the rewritten claims 42 and 45 clearly show

that Leitz and Gori are not similar to applicant. Applicant's invention with novel physical structure and ultra-high fiber (at least 7 grams per serving) is unobvious over Leitz and Gori under Sec. 103.

Applicant's invention's ability to deliver 7 grams of fiber per serving comprising 3 specific fibers once or more daily, is valuable and results in new and unexpected health benefits. Leitz does not teach weight loss, Gori teaches weight control by a total different method of operation from applicant. This clearly proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

**THE NOVEL PHYSICAL FEATURES OF CLAIMS 42 AND 45 ARE UNOBVIOUS AS
OFFICE ACTION DOES NOT PRESENT A CONVINCING LINE OF REASONING**

Applicant respectfully does not see the line of reasoning offered that makes applicant's invention obvious. Applicant has rewritten claim 16 as claims 42 and 45 to more clearly show the novel physical structure that is essential to the method claim.

Applicant respectfully does not understand how a combination of Leitz's and Gori's invention can be combined, and even if combined, could make applicant's invention obvious. Leitz and Gori cannot even be combined as they are independent patents that stand on their own and do not suggest combination. Leitz teaches a balanced fiber composition that provides benefits of fiber at **only** modest dose, and Gori teaches a weight control formulation made of balanced fibers supplemented with minerals that is sprinkled on food 10 doses per day. Leitz recommends inert non-toxic carriers to make his invention liquid, but prefers a pill form. Gori teaches a powder that must be sprinkled on foodstuff prior to eating. Neither recommends more than 5 grams per serving as they are concerned fiber above this dosage may be dangerous. Gori teaches that all fibers are not equal and that the variety of bran, specifically oat, corn and wheat offer special properties and are mandatory for his weight control substance. Leitz teaches the need for 9 fibers to make a balanced fiber composition and that the **benefits of increased fiber are not without**

risks and it is critical to keep in mind that very large amounts of fiber interfere with the absorption of other nutrients. (Column 1 lines 59-68) Gori teaches that **minerals must be supplemented into the formula to replace the minerals that are related or sequestered by the fibers.** (column 2 lines 3-7).

Combining these references would result in a **balanced** fiber formulation containing a minimum of 12 fibers, specific ratios of fiber, **a non-toxic carrier, and minerals.** Applicant does not understand where it would go from here as Leitz can make a liquid (only if inert carriers are used) or powder but prefers a pill, Gori teaches only a powder that is sprinkled on foodstuff with each meal. Leitz prefers 9 fibers, Gori 7 and there are differences. **Applicant's invention does not require balanced fibers, fruit or vegetable fibers, minerals, wheat, or corn bran fiber, or a non-toxic carrier. Applicant's invention's preferred embodiment is a beverage that delivers ultra-high fiber (at least 7 grams per serving) that does not immediately gel.** Applicant's invention is preferably taken **60-30 minutes prior to eating**, not sprinkled on all foodstuff even spaced throughout the day using 10 packets or more.

It is essential that an individual using **Gori's weight control formulation adopt a proper diet, reduce fats, sugar and calories in general.** (Column 4 lines 11-13). One would have to wonder whether any weight control is coming from his formulation or from the dieting that must take place! Applicant's invention requires no special diet or food restriction.

Office action states that it would have been obvious to provide a fibrous composition that would be capable of providing the recommended dosage of 25-40 grams of fiber a day. While it can be argued that current guidelines recommend that level of fiber per day, it is not obvious to **deliver an ultra-high fiber (at least 7 grams per serving),** in fact both Leitz and Gori teach away from this—Gori teaches small packets providing 10 or more evenly spaced throughout the day. **It is unobvious that ultra high dose fiber per serving (7 grams or greater) can be delivered in a well tolerated non dangerous form.** All prior art teaches against delivery of an ultra-high fiber (at least 7 grams per serving) in one serving. The dangers and side effects of too high a level of

fiber per serving are well known in prior art. Applicant further proves this by the NCEP ATP III 2001 guidelines which show that previous research delivered 5-10 grams of fiber per day maximum. (V20-21) **It is also unobvious that ultra high fiber could be delivered without supplemental minerals. Most importantly it is unobvious that 7 grams of fiber or greater could be provided in a beverage form without special processing or inert carriers that does not immediately gel.**

Applicant has novel physical structure and teaches a supplement that differs in structure and function than Leitz and Gori. Applicant submits that the rewritten claims 42 and 45 clearly show that Leitz and Gori are not similar to applicant. Applicant's invention with novel physical structure and ultra-high fiber (at least 7 grams per serving) is unobvious over Leitz and Gori under Sec. 103.

Applicant respectfully feels that no convincing line of reasoning as to why the claimed subject matter as a whole, including the differences over the prior art would have been obvious over the combination of Leitz and Gori. Applicant has rewritten the claim 16 to claim 42 and 45 to clearly show the novel physical features that proves applicant's physical structure and method of delivering ultra-high fiber (at least 7 grams per serving) comprising 3 specific fibers, is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS UNDER SEC. 103

Independent method Claim 18 has been cancelled and rewritten as independent method claim 53.

Claim 18 was rejected under 35 U.S.C 103(a) as being unpatentable over the combination of Leitz (US patent 4,877,627) and Gori (US patent 4,784,861)

Claim 53 teaches a method of reducing the risk of developing and aiding in the treatment of cardiovascular disease in a mammal by improving at least one of the following cardiovascular risk factors, including serum cholesterol, lipoproteins, lipids, triglycerides, high sensitivity C-reactive protein, and homocysteine comprising orally administering a nutritional supplement containing at least seven grams of fiber per serving to a mammal comprising:

- (a) a mixture of guar, oat, and psyllium ,and
- (b) at least one flavoring agent, and
- (c) administering said supplement at least one time daily.

LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR COMBINATION, MUCH LESS THE MANNER PROPOSED

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior- art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a

court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.... *Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness Only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that ‘would lead’ that individual ‘to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant’s invention without also providing evidence of the motivating force which would impel one skilled in the art to do what

the patent applicant has done.”

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states “Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake.” (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant’s invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant’s novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently.** Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant’s invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori’s fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would

question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant's because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

"That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention."

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P. 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, *supra*, a "factual basis to support his conclusion that it would have been obvious" to make the combination.

Applicant argues that Leitz and Gori cannot be combined. They are both independent patents that do not suggest they can be combined, they are both references that are individually complete, they teach away from a suggested combination, and they cannot be combined based on their requirements. Importantly Gori uses the term "consisting of" in describing his main

claim which teaches his formulation is closed ended and CANNOT be combined. Leitz uses the open-ended term “comprising of” to describe his main claim and that indicates that his composition must include **AT LEAST** his requirements. Many of the requirements of Leitz and Gori are mutually exclusive and even though applicant submits they cannot be combined, but even if they were combined, how can it be obvious to know what to combine? Gori teaches oat, corn, and **wheat** are a necessity, Leitz does not teach wheat but instead oat, corn and **barley** bran. Even if all the different fibers are added there would be at least 12 different fibers and there could be potential interactions with the fibers, which would increase clumping or gelling, or make it difficult to sprinkle on food. **Leitz requires 30-48.5% of fiber to come from the fruit and vegetable group, Gori teaches at most 15%.** Gori teaches 14.6% (column 9 table showing fiber content in grams in formulation of cutin and pectin = $3.0+1.9/33.4=14.6\%$ and % of fruit and vegetable group in column 10 table is $10+15/100=15\%$ fiber from the fruit and vegetable group. **If Gori teaches 15% and Leitz 30-48.5% of fiber must come from the fruit and vegetable group then they teach mutually exclusive information.** How can combining mutually exclusive information be obvious?

Applicant stresses both references **teach away from high fiber** and though offer their fiber formulation in up to 5 grams per serving, realistically teach 3-3.3 grams maximum fiber per serving (Leitz 1-3 grams and Gori 1-3.3 grams which includes mineral weight). Applicant wishes to note that the 0.5-5 gram per packet for Gori is his entire formulation of which includes his mineral supplements, the fiber component would be somewhat less.

The following combination of Leitz and Gori would have to contain at least the following based on the two patents:

1. a maximum of 5 grams of fiber per serving
2. at least oat, corn, barley, and wheat brans
3. the cereal component would have to make up 30-48.5% of the final fiber weight,
4. **30-48.5% fiber from the fruit and vegetable group (Leitz) , 15% maximum (Gori)**

5. lemon, acerola, and carrot pulp
6. 3-40% of the other fibers not from fruit, vegetables, or cereals
7. mineral supplements **manganese, selenium, zinc, copper, iron and calcium**
8. Must be administered throughout the day sprinkled on foodstuffs.
9. Served as a powder, tablet, chewable tablet, granules, or bulk powder. (A 2 gram fiber per serving beverage requiring liquid food product to ease administration is described by Leitz but not claimed) The only overlap between Leitz and Gori regarding administering the supplement is the granules or powder sprinkled on food.

Applicant

1. Minimum of 7 grams of fiber per serving
2. At least oat, guar, and psyllium and does not require any other fibers
3. No mineral or nutrient replacement requirements
4. Taken in one or more doses typically 30-60 min before food or instead of food, not with food.
5. Preferred is a drink, but could be served in a pudding snack bar, wafer or dog bone (Dependent claims 56 and 57).

Applicant's invention is unobvious. Applicant provides a method of reducing the risk of developing and aiding in the treatment of cardiovascular disease in a subject by improving one or more of the following including, serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine comprising orally administering the ultra-high fiber (at least 7 grams per serving) supplement comprising guar, oat, psyllium and at least one flavoring agent one or more times daily. **Leitz only comments that soluble fiber is associated with LDL and serum cholesterol reduction. Gori suggests his invention provides other well known benefits of fiber including reduction in cholesterol and triglycerides to prevent heart diseases. Gori requires a proper diet with reduced fats, sugars, and calories and increased consumption of fruits, vegetables, and nuts. There is no proof that Gori's weight control supplement provides any cholesterol, triglyceride, or heart disease benefit as the**

benefits would be due to the proper diet one has to adopt. If his formula worked to reduce cholesterol, triglycerides and heart disease, then it would have to be independent of dietary changes that are well known to provide these exact benefits. There is no proof, method, or evidence that the type of fibers used in both Leitz and Gori actually provide any cholesterol benefits at all. National guidelines show 5-10 grams of soluble fiber can reduce LDL by 5%. There is no proof that these exact formulas delivering 1-3 grams of fiber per serving with their specific variety of fibers actually produce these benefits.

Applicant's invention has a novel physical structure that provides new and unexpected results. Importantly, it does not require food restriction or avoidance, reduction of fats, sugars, or calories, or an increased consumption of fruits, vegetables, and nuts (as required by Gori). Applicant's invention does not require more than 3 fibers and does not require a balance of fibers. It does not require minerals and nutrients. It is not required to be consumed with foodstuffs. Applicant's invention can be used to promote dramatic weight loss, dramatic reduction in risk of cardiovascular disease, or both. In it's preferred embodiment a zero calorie beverage delivering ultra-high fiber (at least 7 grams per serving) that does not immediately gel and can be taken one or more times daily to dramatically improve LDL cholesterol, LDL lipoprotein, triglycerides, high sensitivity C-reactive protein, homocysteine, HDL cholesterol, and HDL lipoproteins.

NECP ATP III guidelines issued 2001 show that soluble fiber when taken at a **5-10 gram** per day dose results in an **approximate 5% reduction in LDL cholesterol**. Investigators report that soluble fiber produces a **reduction in HDL cholesterol**...other reviews report little, no or inconsistent effect on HDL cholesterol. (V20-V21)

Leitz reports that it is generally accepted that soluble fiber is associated with a reduction in LDL and serum cholesterol. Leitz does not teach how his balanced fiber composition actually produces these benefits. Applicant is a board certified internal medicine physician and lipid expert who teaches other doctors advanced cholesterol evaluation and management. Applicant

submits that just having soluble fibers in a formulation, does not guarantee that LDL or serum cholesterol will be reduced, or that it will be reduced significantly. The type or types of fiber, the amount of each fiber, the delivery, and the other ingredients within the formula (some of which could bind certain fibers) all play a role in the effectiveness of cholesterol reduction. Leitz teaches a balanced fiber composition that is administered in modest levels of fiber per serving that does not exceed 5 grams [preferred 1-3 grams] per serving. Essential to Leitz are 3 groups of fiber, 9 fibers in total, and specific ratios of each of the three groups.

Gori provides a weight control formulation that requires 7 fibers and additional specific minerals. His formula must be sprinkled on all foodstuffs throughout the day and an average weight person will require 10 packets, those of higher weight, will require more packets. Gori teaches that his packets will contain 0.5- 5 grams, and that weight is a combination of fiber, minerals and excipients. He prefers 1-3.3 grams per packet. He teaches that 10 grams of fiber administered in 10 packets per day is expected for an average weight person. He teaches against going more than 5 grams per serving. Gori teaches his formula will achieve the well known benefits of fiber including reducing cholesterol and triglycerides and preventing heart disease. Applicant submits that just having soluble fibers in a formulation, does not guarantee that LDL or serum cholesterol will be reduced, or that it will be reduced significantly. The type or types of fiber, the amount of each fiber, the delivery, and the other ingredients within the formula (some of which could bind certain fibers) all play a role in the effectiveness of cholesterol reduction. Applicant respectfully submits that Gori's teaching as to the benefits of his invention are overly optimistic such as "achieve all known benefits of fiber". **Gori requires a proper diet with reduced fat, sugar, and calories to provide benefits of his invention. Applicant respectfully submits that any cholesterol reduction may be due to the reduced fat, sugar and calories, and not Gori's invention itself. Gori does not provide a method of cholesterol improvement or cardiac risk prevention (Gori does not say that more packets are needed for people with worse cholesterol, he only bases the number of packets on the weight of an individual) .**

Leitz and Gori cannot be combined, but even if combined would not have a structure anything like applicant's novel physical structure. Leitz and Gori do not anticipate applicant's invention and the dramatic effects the applicant receives with his novel structure could not have been obvious even when national guidelines are reviewed.

Applicant's physical structure is much different than Leitz, Gori or the combination of the two and provides dramatic health benefits which are very important, valuable and unexpected, clearly proving that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO UNEXPECTED RESULTS

Applicant's invention with novel physical structure is an ultra-high fiber (at least 7 grams per serving) supplement comprising 3 specific fibers each with specific physical characteristics and unique physical properties allowing a subject to consume a minimum of 7 grams per serving once or more daily. **Applicant's invention has new and unexpected results.** National guidelines (NCEP ATP III 2001) teach that 5-10 grams of soluble fiber gives approximately a 5% reduction in LDL cholesterol, and that soluble fiber reduces HDL or gives little, no, or inconsistent results. Applicant, a board certified internal medicine doctor and lipid expert, who teaches other doctors advanced cholesterol evaluation and management, has documented spectacular results with regard to cholesterol both LDL and HDL, triglycerides, lipoproteins, high sensitivity C-reactive protein, and homocysteine. These dramatic reductions individually are well known to dramatically reduce cardiovascular risk, and in combination the risk reduction is even greater. Whereas, national guidelines teach 5% reduction in LDL cholesterol, applicant has seen LDL drops of up to 60%, triglyceride drops of up to 82%, and HDL increases of up to 56% (22 points). (It is well accepted that for every 1 point increase in HDL cholesterol, cardiovascular risk is reduced 3-4%). Applicant also has documented maximal improvement in high sensitivity C-reactive protein levels whereby patients with high values of high sensitivity

C-reactive protein (quintile 5 the worst risk), were lowered to quintile 1, the least risk of cardiovascular disease. It is important to note that high sensitivity C-reactive protein is an independent risk from an individual's cholesterol level in determining cardiovascular risk. Applicant's invention has dramatically lowered both lipid and the inflammatory risk from high sensitivity C-reactive protein in numerous individuals. Applicant's invention has allowed individuals to reduce cholesterol medication or eliminate the need for them entirely. At times multiple medications have been stopped with long term success. Applicant also notes a case of an individual whose cholesterol could not be optimized on 3 cholesterol medications that were at maximum dose. After 2 months on applicant's invention and off all cholesterol medications, the individual had optimized cholesterol results that have remained optimized without the need for medication.

It is clear from Leitz and Gori that applicant's physical structure is very different, applicant comprises 3 fibers with specific physical characteristics and properties and at a dose of a minimum of 7 grams of fiber per serving. Leitz and Gori teach a maximum of 5 grams of fiber per serving but recommend a much lower number of grams of fiber per serving. Both teach away from high fiber due to dangers of side effects and concern of mineral deficiencies. Gori requires minerals in the invention and his invention must be taken by sprinkling on all foodstuffs throughout the day.

It is clear applicant's novel physical structure has provided a method of delivering ultra high dose fibers that offer dramatic cardiovascular risk reduction that is much more valuable than current scientific guidelines would suggest. **Cited references Leitz and Gori do not offer a method of cardiovascular risk prevention, improvement in HDL, or high sensitivity C-reactive protein.** Applicant, a lipid expert, submits that there is no evidence that Leitz provides cholesterol reduction or significant reduction, and that Gori provides no evidence his formulation will do the same. Gori's formulation cannot be attributed to lower cholesterol or reduce risk of cardiovascular disease when he requires reduction in fats, sugars, and calories and an increased consumption of fruits and vegetables. Applicant's invention with novel structure, and benefits

that greatly exceed national guideline's expected results prove applicant is unobvious over Leitz and Gori and under sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO ASSUMED UNWORKABILITY

Up to present time those skilled in the art have not produced a liquid beverage that contains a minimum of 7 grams of fiber per serving. Combining fibers in high dose results in immediate gelling. No commercial beverage is available containing a minimum of 7 grams of fiber as no one skilled in the art has found a way to put so much fiber in a serving without having it immediately gel. Leitz and Gori actually teach away from high dose fiber over concerns of dangerous side effects, kelation and sequestering of minerals by high doses of fiber. Applicant's invention using specific fibers with special physical characteristics and properties allows applicant's invention to contain an ultra-high fiber (at least 7 grams per serving) that can be consumed as a liquid beverage without immediate gelling. Applicant's invention does not require inert carriers, minerals, supplements or excipients to prevent gelling.

Up to present time those skilled in the art have not produced a fiber product that could lower LDL cholesterol more than about 5%. Applicant's invention with novel physical structure is an ultra-high fiber (at least 7 grams per serving) supplement comprising 3 specific fibers each with specific physical characteristics and unique physical properties allows a subject to consume a minimum of 7 grams per serving once or more daily. Applicant's preferred embodiment allows for a zero calorie beverage to be made. Applicant's invention dramatically reduces cardiovascular risk by improving LDL and HDL cholesterol, lipoproteins, triglycerides, high sensitivity C-reactive protein, and homocysteine.

Applicant's invention allows for **compliance** in consuming ultra high doses of fiber. It is pleasant tasting and more than 14 grams of fiber [17 grams with preferred alternative embodiment] can be consumed in two beverages each containing at least 8 ounces of liquid.

Leitz and Gori use different fibers and require a balance of fibers, which necessitates using 7-9 fibers. Gori also requires minerals to be added to the invention. Leitz can make a liquid fiber supplement but it requires an inert carrier and contains only 2 grams. **It would have been unobvious to make a supplement using fewer fibers** when Leitz and Gori teach a great variety of different fibers are needed. **It would have been unobvious to use much more fiber than Leitz and Gori teach, especially when they warn of risks and dangers** to the organism. Likewise, it would have been unobvious to create a liquid beverage containing a minimum of 7 grams of fiber that does not require liquid food product for ease in administration.

Applicant's invention overcomes prior arts inability to deliver ultra high doses of fiber per serving and provides a method of reducing cardiovascular risk through consuming the novel invention once or more daily. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO ASSUMED INSOLUBILITY

Up to present, those skilled in the art have avoided high doses of fiber due to gastrointestinal side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Leitz column 1 58-63). **Gori's balanced fiber supplement necessitates the addition of "major minerals".** (Gori column 2 lines 3-7 and column 3 line 19-22)

Applicant, a board certified internal medicine physician has communicated with numerous patients, and buyers of his invention who take **more than 14-28 grams** of fiber per day, **without significant side effects or any evidence of nutrient deficiency.**

Up to present, cardiovascular risk reduction takes place by individuals making a number of lifestyle modifications including taking a cholesterol restricted diet, daily exercise program, reducing weight, and taking prescription medications. Many individuals do not have the time, will power, or financial resources to successfully make these changes. Natural products such as plant sterols, stanols, soy, and fiber have been used with mild success. National guidelines NCEP ATP III guidelines note that 5-10 grams of soluble fiber produce about a 5% reduction in LDL cholesterol and lowers HDL cholesterol. Fiber supplementation produces a small and many times insignificant reduction in cardiovascular risk. Applicant's invention has provided a new solution. Applicant's invention allows individuals to get potentially dramatic improvement in LDL and HDL cholesterol, lipoproteins, triglycerides, high sensitivity C-reactive protein, and homocysteine by taking his novel fiber beverage one or more times daily. Dramatic LDL lowering of up to 60%, triglyceride reductions of up to 82%, and elevations in HDL of up to 56% leading to a great improvement over fiber used in scientific studies and is totally unexpected. Applicant's novel physical structure allows this to occur.

Numerous individuals have high triglycerides that greatly accelerate the risk of cardiovascular disease yet have difficulty in lowering them through diet, exercise and medications. Applicant teaches other doctors advanced cholesterol evaluation and management and teaches that high triglycerides makes smaller more atherogenic particles (small lipoproteins) greatly increasing the risk of heart disease. Applicant's invention gives dramatic triglyceride reductions of up to 82%. Applicant's novel physical structure is responsible for this benefit.

Up to present treatment of high sensitivity C-reactive protein has been rather limited. Current strategies for lowering high sensitivity C-reactive protein include smoking cessation, weight reduction, exercise, aspirin, and prescription (statin) drugs. Many individuals do not have the will power, or financial resources to incorporate them into their daily living. The majority of patients fear taking medication [statins or niacin] they feel may adversely affect their liver. Up to present, elevated levels of high sensitivity C-reactive protein have been difficult to treat.

Applicant's invention can dramatically lower high sensitivity C-reactive protein and can even

provide the maximum improvement by lowering individuals from the highest quintiles to the lowest quintile corresponding to the highest risk of cardiovascular disease to the lowest risk. . This is an unexpected result not previously described with fiber. Applicant's novel physical structure and ability to deliver ultra high dose fiber per serving of very specific fibers allows dramatic improvement in high sensitivity C-reactive protein levels and ultimately in reducing cardiac inflammation.

Leitz does not teach that his invention reduces cardiovascular risk. He only makes the statement that soluble fiber reduces low density lipoprotein and serum cholesterol at least in the short term. Gori claims his invention achieves the benefits of reducing blood cholesterol and triglycerides [misspelled]. Applicant respectfully argues that this cannot be assumed. Even the national guidelines which teach using 10 grams of fiber only resulted in a 5% reduction in LDL cholesterol. There is no support that individuals take his 10 doses per day, a compliance nightmare. **There is no support for cholesterol and triglyceride lowering.** Gori teaches his invention should enjoy the benefits attributed to fiber, but **his invention makes adopting a proper diet, reducing fats, sugars and calories in general a requirement! He also teaches to eat more fruits, vegetables and nuts.** One cannot attribute cardiovascular risk reduction to his invention as it requires dietary changes that are known to provide cardiovascular risk reduction alone. **Combining these two references, which do not as individual references reduce cardiovascular risk, will not somehow give cardiovascular risk reduction by combining them.** Regardless, applicant's novel physical structure is different and provides a method for cardiovascular risk reduction.

The unexpected and superior results of applicant's invention in reducing risk of cardiovascular disease clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO A COMMERCIAL SUCCESS

See Declaration Under Rule 132.

Applicant's novel structure and resulting functions and benefits has allowed applicant to be commercially successful by word of mouth advertising with little or no formal advertising while maintaining a solo medical practice. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO LEITZ AND GORI BEING PAPER PATENTS

Applicant respectfully believes Leitz's and Gori's inventions are "paper patents" that have not been made commercially. Applicant's invention is commercially successful due to its novel physical structure and the dramatic health benefits it produces. Numerous individuals are taking applicant's invention strictly for the lipid benefits and the cardiovascular risk reduction. Many have reduced the need for cholesterol medications or eliminated the need entirely.

Leitz and Gori are patents at least 10 years old. Applicant, a physician, and lipid expert, is unaware of Leitz or Gori being sold commercially. Applicant believes they are paper patents and should be construed narrowly.

Applicant's novel structure is commercially successful whereas Leitz and Gori are paper patents, proving applicant's novel structure and that it is unobvious under Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO CROWDED ART

Cardiovascular disease is a multi-billion dollar expense in the United States. It is estimated that 60-70% of people who need cholesterol treatment do not get it. Billions are spent by consumers

on both prescription and non-prescription cholesterol reducing products. This is a very crowded art. Applicant's invention with novel physical features produces new and unexpected results including **dramatic** reductions in cholesterol, triglycerides, lipoproteins, high sensitivity C reactive protein and homocysteine. Each of these novel steps should be regarded as significant.

Applicant's invention has allowed numerous individuals to reduce their cholesterol medications or eliminate them completely. The individuals enjoy improved health and longevity, reduced prescription costs, and avoid the side effects of prescription drugs.

Leitz does not teach that his invention reduces cardiovascular risk. He only makes the statement that fiber is associated with reduction in LDL and serum cholesterol at least in the short term. Gori claims his invention achieves the benefits of reducing blood cholesterol and triglycerides [misspelled]. Applicant respectfully argues that this cannot be assumed. National guidelines teach us that even using 10 grams of fiber only resulted in a 5% reduction in LDL cholesterol. There is no support that individuals who take his 10 doses per day have documented benefit. **There is no support for cholesterol and triglyceride lowering. In fact, having to sprinkle Gori's formula on food stuffs 10 times per day is likely to increase carbohydrate consumption and raise triglycerides.** Gori teaches his invention should enjoy the benefits attributed to fiber, but **his invention makes adopting a proper diet, reducing fats, sugars and calories in general a requirement!** (Column 4 lines 5-12). One cannot attribute cardiovascular risk reduction to his invention as it requires dietary changes that are known to provide cardiovascular risk reduction alone. Both Leitz and Gori cannot be assumed to lower LDL or serum cholesterol, and even if they did, cannot be assumed to reduce it significantly. There is no proof that the fibers in their formulas at the doses provided, and with the additional ingredients added will guarantee reduction in cholesterol. The specific fiber type, weight per serving, and additional admixed components all weigh into the effectiveness of cholesterol reduction. Combining these two references which individually do not reduce cardiovascular risk will not somehow give cardiovascular risk reduction.

Applicant respectfully questions whether Gori's invention itself can reduce cholesterol when his invention requires the reduction of fats, sugars, and calories and increased consumption of fruits and vegetables which are known to produce cholesterol benefits themselves.

Applicant's invention has novel physical structure over Leitz and Gori and produces dramatic cardiovascular risk reduction, cost savings, and reduces the chance of medication side effects. This should be regarded as valuable in a very crowded art. This clearly proves that the applicant's novel structure is unobvious over Leitz and Gori under section 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO OMISSION OF ELEMENT(S)

Applicant's invention contains **as few as 3 fibers** (guar, oat, and psyllium) each having specific physical characteristics and properties. Applicant's invention is a minimum of 7 grams of fiber per serving. **Leitz's invention contains 9 fibers and requires a non-toxic inert carrier to make it liquid.** (Column 4 lines 45-52). Leitz requires a complicated fiber formulation modeled after the basic food groups and balanced after the basic food groups (Column 2 lines 37-47). **Gori's invention contains 7 different fibers** and he teaches the importance of having 3 specific types of bran (oat, wheat, corn) (table Fiber Formula column 4) **Gori's invention requires minerals to be added as well. Gori's invention is a food additive sprinkled on all meals.**

Applicant's invention can use as few as three fibers, does not require corn wheat or barley bran which are mandatory to the references. Applicant does NOT require administration with consumption of food, minerals, or an inert carriers, lubricants, or binders. Applicant's invention delivers a minimum of 7 grams of fiber per serving one or more times daily. Typically patients take 1 serving (based on 2 scoops per serving) which provides a **minimum of 14 (preferred 17) grams of fiber in two doses.** Leitz and Gori, require multiple doses based on their preferred unit dose administration of 1-3 grams for Leitz (2 grams in bulk powder form) (column 5 lines 40-43) and Gori's preferred 1- 3.3 grams-10 times per day (column 3 lines 53-56

and column 4 lines 64-67) . **Applicant believes that limiting the number of times the fiber must be consumed is a significant advantage and improves compliance.**

Applicant's invention is much simpler, cleaner, and easier to use than Leitz and Gori and provides documented cardiovascular risk reduction. . Applicant's invention does not require a fiber balance, but instead comprises 3 fibers with certain physical structure and properties. Applicant's novel physical structure comprises an ultra-high fiber (at least 7 grams per serving) supplement, where as the references recommend a maximum of 5 grams and prefer only 1-3 grams of fiber per serving. Applicant does not require specific fibers required by references including acerola, lemon and carrot pulp, wheat, corn, barley, and soy bran, cutins etc. Applicant does not require mineral supplementation. Applicant provides for increased compliance due to the need to take fewer servings per day. Applicant's invention novel physical structure and omission of several elements clearly proves it is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO UNSUGGESTED MODIFICATION

Leitz and Gori lacks any suggestion that either reference should be modified in a manner to meet claim 53. Leitz and Gori both seek to imply that their invention shares the benefits of fiber that are well accepted. **This cannot be implied.** Scientific results show fiber can reduce LDL cholesterol by about 5%. This is based on scientific studies of specific soluble fibers that were given in 5-10 gram per day doses. **Using different dosages, different fibers, or different ingredients admixed with the fiber would change the results.** Both references are independent, complete and stand-alone patents. They do not suggest they should be combined or modified in any manner. Combining them does not seem possible as Gori must be in packet powder form that is sprinkled on all foodstuffs throughout the day, Leitz does not require sprinkling on foodstuffs. Gori requires minerals, Leitz does not. Gori requires at least oat, corn, and wheat bran ,Leitz requires oat, corn and barley bran instead. Leitz requires 30-48.5% of the fiber weight to come from fruit and vegetable group, Gori teaches 15%. These are just some of

the differences. Applicant questions how it would be obvious to try to combine these two references that teach different requirements some of which are mutually exclusive? Applicant submits even if combined, applicant's novel structure and function are vastly different than the cited references.

Combination of Leitz and Gori requires unsuggested modifications. Applicant's novel structure is different than Leitz and Gori and unobvious under Leitz and Gori under Sec. 103

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO UNAPPRECIATED ADVANTAGE

Up until present, those skilled in the art were unaware of the dramatic weight loss and lipid benefits from serving applicant's novel supplement comprising 3 specific fibers and administration of a minimum of 7 grams of fiber serving once or more daily. While it is generally recognized that fiber is healthy, can reduce LDL cholesterol, and could reduce some forms of cancer, the **dramatic** weight loss, and **dramatic** reductions in risk of cardiovascular disease through providing applicant's invention once or more daily have been unappreciated.

Fiber is well known to lower LDL cholesterol but current belief is that consuming 5-10 grams of viscous fiber only results in a 5% reduction in LDL cholesterol. (NCEP ATP III guidelines 2001 V21). Oat and psyllium have shown reduction in HDL cholesterol (Anderson 1995) and other reviews show little, no, or inconsistent HDL results. (NCEP ATP III guidelines 2001 V21). High sensitivity C-reactive protein is an independent risk factor for cardiovascular disease. Fiber is not a medically known treatment.

Applicant's invention produces an unappreciated advantage. Applicant's invention with novel physical structure is an ultra-high fiber (at least 7 grams per serving) supplement comprising 3 specific fibers each with specific physical characteristics and unique physical properties that allows a subject to consume a minimum of 7 grams per serving once or more daily.

Instead of the known 5% LDL cholesterol reduction, applicant's invention provides up to a 60% reduction, and triglyceride reductions of up to 82%. Instead of HDL reduction, applicant's invention produces HDL elevations of up to 22 points (a 56% elevation). Applicant's invention produces improvement in high sensitivity C-reactive protein levels by lowering the levels and can maximally lower cardiac inflammation and the risk of cardiovascular disease.

Leitz does not teach that his invention reduces cardiovascular risk. He only makes the statement that it is generally accepted fiber reduces LDL and serum cholesterol at least in the short term. Gori claims his invention achieves the benefits of reducing blood cholesterol and triglycerides [misspelled]. Applicant respectfully argues that this cannot be assumed. National guidelines teach us that even using 10 grams of fiber only resulted in a 5% reduction in LDL cholesterol. There is no support that individuals who take his 10 packets per day have documented benefit. **There is no support for cholesterol and triglyceride lowering.** In fact, taking Gori's formula 10 times a day can increase carbohydrate consumption and increase triglycerides. Gori teaches his invention should enjoy the benefits attributed to fiber, but **his invention makes adopting a proper diet, reducing fats, sugars and calories in general a requirement!** (Column 4 lines 5-12). One cannot attribute cardiovascular risk reduction to his invention as it requires dietary changes that are known to provide cardiovascular risk reduction alone. **Combining these two references which do not reduce cardiovascular risk will not somehow give cardiovascular risk reduction.**

Applicant respectfully questions whether Gori's invention itself can reduce cholesterol when his invention requires the reduction of fats, sugars, and calories and the increased consumption of fruits, vegetables and nuts which are known to produce cholesterol benefits themselves.

Applicant's invention produces unappreciated advantages over prior art. Applicant's novel physical structure produces unappreciated advantages over Leitz and Gori which clearly proves the novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO LACK OF IMPLEMENTATION

If applicant's invention was in fact obvious, because of its advantages, those skilled in the art surely would have implemented it by now. The fact that those skilled in the art have not implemented applicant's invention despite its great advantages, indicates that it is not obvious. Prior art has used oat, guar and psyllium fibers, but no prior art has taught how to use these fibers with specific physical structure and properties so as to safely administer an ultra-high fiber (at least 7 grams per serving) supplement or create a beverage containing a minimum of 7 grams of fiber per serving that could be easily taken in one or more daily doses and produces dramatic cardiovascular risk reduction. No prior art has described how to make a zero calorie fiber beverage that contains 7 or more grams of fiber and can be taken safely one or more times daily without danger to the mammal.

If using 7 or more grams of fiber per serving was obvious, Leitz and Gori would have surely taught that in their patent. The fact that they taught a range of 0.5-5 grams per serving and **that they preferred a much smaller number of grams per serving indicates applicant's invention was unobvious.** Applicant submits that Leitz uses "about 5 grams" should not be interpreted to mean more than 5.49 grams for two reasons. If Leitz wanted more than 5 grams he would have stated about 6, or about 10 etc. 5.49 rounds up to 6 which is still less than applicant's minimum of 7 grams. **Furthermore, Leitz did not mean for his serving to be more than 5 grams as evidenced by his preferred gram per serving of 1-3 grams, and 2 grams if it is a beverage, all significantly lower than the 5 gram maximum he teaches.** While prior art has used guar, oat, and psyllium none has combined the three fibers with the physical characteristics and properties as applicant has done. No prior art has made a zero calorie beverage containing at least 7 grams of fiber per serving that does not immediately gel.

The lack of implementation of the applicant's invention along with its novel physical structure clearly proves applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS DUE TO MISUNDERSTOOD REFERENCE

Applicant cancelled claim 18 and rewrote new claim 53 to more clearly show the novel structure and particularly define the invention in a patentable manner over the cited prior art.

As described above, applicant respectfully submits that Leitz and Gori are misunderstood references, as they are very different in structure and function from applicant.

There is no logical way to combine the two cited references, and applicant submits that both are independent, complete and stand alone references. If they were understood, they would not be combined.

Applicant teaches novel fiber supplement that comprises an ultra-high fiber (at least 7 grams per serving) formula that comprises guar, oat, and psyllium. It can be made into a liquid beverage, a zero calorie liquid beverage, both which do not immediately gel. It can be made into a pudding, snack bar, wafer, or dog bone.

Leitz and Gori teach a balanced fiber composition that requires a great variety of fibers, with specific ratios, specific fibers not required by applicant, minerals, and method of administration different than applicant's. Both Leitz and Gori teach a **maximum** of 5 grams of fiber per serving and the dangers of serving a higher level of fiber.

Applicant has novel physical structure and teaches a supplement that differs in structure and function than Leitz and Gori. Applicant submits that the rewritten claim 53 clearly shows that Leitz and Gori are not similar in structure or function to applicant. Applicant's invention with

novel physical structure and ultra-high fiber (at least 7 grams per serving) is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS AS THEY PROVIDE A SOLUTION TO A LONG-FELT AND UNSOLVED NEED

It is well accepted that one half of Americans die of cardiovascular disease. More than half the adult population in the United States has cholesterol levels above desirable levels.

Applicant's novel physical structure serving an ultra-high fiber (at least 7 grams per serving) and comprising 3 specific fibers with unique physical characteristics allows special advantages. Applicant's supplement delivers ultra-high fiber (at least 7 grams per serving) in an easy to take manner without danger to the mammal. Applicant's supplement can be admixed with a liquid to make an ultra-high fiber (at least 7 grams per serving) beverage that will not immediately gel. When water is used as the liquid a zero calorie beverage is created. This invention solves several long-felt and unsolved needs, including how to lower risk of cardiovascular disease without dieting, exercise, or using prescription medications. Many individuals prefer to use a natural means to lower their cholesterol. Many wish to dramatically lower cholesterol without prescription drugs.

Applicant's novel structure allows delivery of ultra-high dose fiber per serving that brings dramatic improvement in many risk factors for cardiovascular disease. Applicant has documented improvement in serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine. Individual improvements give a significant decrease in cardiovascular risk prevention, multiple improvements give much greater reduction of risk. The majority of the users take one serving (2 scoops each having more than 7 grams of specific fibers). The ease of use and the ability to deliver more than 14 grams of fiber in as few as two beverages per day greatly improves results and compliance.

Leitz does not teach that his invention reduces cardiovascular risk. He only makes the statement that fiber reduces low density lipoprotein and serum cholesterol at least in the short term. Gori claims his invention achieves the well known benefits of reducing blood cholesterol and triglycerides [misspelled] to prevent heart disease. Applicant respectfully argues that this cannot be assumed. Even the national guidelines teach using 10 grams of fiber only resulted in a 5% reduction in LDL cholesterol. There is no proof that his formula would reduce risk of heart disease even if he had a 5 % reduction in LDL. There is no proof that he could lower cholesterol at all. There is no support that individuals could take his 10 packets per day. **There is no support for cholesterol and triglyceride lowering.** Gori's ten packets sprinkled on food throughout the day would likely increase carbohydrate consumption and increase triglycerides. Gori teaches his invention should enjoy the benefits attributed to fiber, but **his invention makes adopting a proper diet, reducing fats, sugars and calories in general a requirement!** One cannot attribute cardiovascular risk reduction to his invention as it requires dietary changes that are known to provide cardiovascular risk reduction alone. Combining these two references which do not as individual references reduce cardiovascular risk will not somehow give cardiovascular risk reduction by combining them. Applicant, a medical doctor and lipid expert cautions that just because a formula contains soluble fiber does not mean it lowers cholesterol, or lowers it significantly. **The type of fiber, the amount of fiber, and the other ingredients admixed all play a role in the ability for the supplement to improve cholesterol levels.** Furthermore, Leitz and Gori do not teach they can raise HDL, improve lipoproteins, or high sensitivity C-reactive protein. Regardless, applicant's novel physical structure is different, provides much better benefits and provides a method for cardiovascular risk reduction.

Another solution to a long-standing problem is "how can an individual significantly reduce risk of cardiovascular disease without taking prescription medication?" Applicant's novel physical structure of specific fibers with specified characteristics results in a variety of lipid improvements as well as in high sensitivity C-reactive protein. The ability to deliver more than 7 grams of this novel fiber supplement per serving is an important discovery. The fact that more than 14 grams of fiber are delivered in as few as two doses, provides compliance and ease of use

that results in dramatic cardiovascular risk reduction. **Applicant has reduced cholesterol medications in several patients and even eliminated the need for them in some.**

Leitz and Gori cannot be combined but even if they were, they do not offer the cardiovascular risk benefits that applicant does. Leitz only mentions that soluble fiber is associated with LDL and serum cholesterol reduction. No method, proof, or evidence of his formulation containing the preferred 1-3 grams of his formula or 5 grams fiber maximum would produce those results. Applicant, a board certified internal medicine physician and expert in cholesterol therapy, cautions that one cannot assume that Leitz improves cholesterol, as the type, quantity of fiber, method of administration, timing of administration, and other admixed components all play a role as to whether cholesterol improvement occurs. Gori shows no method, proof or evidence he can provide any cholesterol, triglyceride, or risk reduction in heart disease for the same exact reason and the fact that his formula requires a diet low in fat, cholesterol, and calories and rich in fruit, vegetables and nuts. The “proper diet” Gori demands could provide the benefits for cholesterol reduction and cardiovascular risk reduction itself. Leitz and Gori as references could not have made applicant’s structure or new and unexpected results. One cannot take two references that do not offer a variety of cardiovascular benefits, mix them together, and assume that applicant’s cardiovascular benefits would be created. Applicant produces new and unexpected results and is totally unobvious over Leitz and Gori and clear both over Sec. 103.

It is clear that applicant’s invention with novel physical structure provides a method of delivering ultra-high fiber (at least 7 grams per serving) of specific fibers, which provides numerous health benefits that cannot be claimed by the either Leitz or Gori, in individual or in combination. These benefits solve many long-felt and unsolved needs in regard to cholesterol treatment and reduction in cardiovascular risk. These valuable results clearly prove that applicant’s novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 53 ARE UNOBVIOUS AND PRODUCE A CONTRARIAN INVENTION

Applicant's invention is novel in that it allows safe and easy administration of an ultra-high fiber (at least 7 grams per serving) supplement using as few as three specific fibers. This is totally contrarian to Leitz and Gori, which teach to use 5 grams of fiber or less per serving, and that a balanced fiber composition involving many different fibers is necessary. Leitz and Gori teach that high fiber levels are dangerous and that is why they do not exceed 5 grams per serving. Both teach that high fiber prevents absorption of nutrients and minerals. Gori teaches that mineral supplementation is a necessary part of his formulation.

Leitz teaches that it is generally accepted that soluble fiber is associated with reduction in LDL and serum cholesterol. He does not teach cardiovascular risk reduction. Gori states his formula "will achieve other well-known benefits of dietary fiber. Among them are included minimizing the possibility of cancer and preventing certain digestive diseases, reducing blood cholesterol and triglycerides [misspelled] to prevent heart diseases, and other benefits that are scientifically known. Of course it is essential to adopt a proper diet, to reduce fats, sugars, and calories, in general and it is helpful to increase one's consumption of fruit, vegetables and nuts." (column 4 lines 6-13). Applicant, a medical doctor and lipid expert submits that there is no proof that Gori provides the proper fibers in proper gram amounts to give significant reduction in cholesterol or risk of heart disease. His invention requires a proper diet with reduction of fats, sugar and calories—dietary measures known to help reduce the risk of heart disease alone. Because Gori ties his invention to these dietary changes, one cannot assume his invention actually does anything more than the diet would do alone. Applicant also questions the ability of any human to comply with 10 packages daily. **Applicant further submits that Gori does not claim a method of cholesterol reduction or reduction in the risk of heart disease.**

Leitz's and Gori's inventions teach that a balanced fiber formulation is necessary and Gori makes the addition of minerals a further necessity. Leitz teaches to use balanced fiber to provide the benefits of fiber at a modest dose of fiber. Both teach that high doses of fiber are not well tolerated and dangerous. These two references whether individual or in combination teach away

from giving high fiber to a mammal. As further proof of teaching away from delivering high fiber per serving, **Gori, teaches his daily fiber gram dose should be delivered in 10 individual packets that are spaced out with all foodstuffs throughout the day.**

Applicant's invention provides a **method of delivering safe, healthy fiber with a minimum of 7 grams of fiber per serving, with as few as 3 specific fibers** one or more times daily. Fourteen grams or greater of fiber can be delivered in as few as 2 servings. Applicant provides a method for improving serum lipids, HDL, triglycerides and high sensitivity C-reactive protein not taught by Leitz and Gori. Applicant provides a method for Applicant's novel physical structure and ability to deliver ultra-high fiber (at least 7 grams per serving) safely without need for minerals or nutrient supplementation is contrarian to Leitz and Gori and clearly proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 53 ARE UNOBVIOUS DUE TO A NEW PRINCIPLE OF OPERATION

Applicant's invention has blazed a new trail. Applicant's novel structure shows that a variety of health benefits can not only be provided, but maximized through providing an ultra-high fiber (at least 7 grams per serving) fiber supplement that uses specific fibers with specific properties at least one time daily. Applicant has figured a way to deliver ultra high doses of fiber easily to a mammal and has used fibers that provide numerous health benefits including reduction in the risk of cardiovascular disease. Applicant's novel physical structure is **not balanced, does not require mineral supplementation, and can deliver a minimum of 7 grams of fiber per serving safely and easily to a mammal.** One advantage of delivering ultra-high fiber (at least 7 grams per serving), is **that fewer doses are needed to deliver very high amounts of fiber daily.** This results in improved compliance and new and unexpected results with respect to dramatic weight loss and cardiovascular risk reduction.

Applicant's new principle of operation is delivering ultra-high fiber (at least 7 grams per serving) in one or more doses daily. The preferred embodiment is a zero calorie drink that is easy to consume. Typical users of applicant's invention take a beverage, snack bar, pudding, or other solid such as a dog bone at least once daily. The solid and semi solids are accompanied by at least 8 oz of liquid to further hydrate the consumed fiber. The beverage that contains at least 7 grams of fiber per serving, the zero calorie beverage, the pudding, the snack bar, the wafer, and the dog bone are all new principles of operations not taught in Leitz or Gori. The ultra-high fiber (at least 7 grams per serving) is unique and contrary to Leitz and Gori. Applicant's novel physical structure has brought dramatic improvements in improvement in serum cholesterol, lipoproteins, lipids, triglycerides, high-sensitivity C-reactive protein, and homocysteine and reduction in risk of cardiovascular disease.

Leitz teaches that it is generally accepted that soluble fiber is associated with reduction in LDL and serum cholesterol. He does not teach cardiovascular risk reduction. There is no proof that Leitz actually lowers LDL or cholesterol. Applicant, a medical doctor and lipid expert cautions that just because a formula contains soluble fiber does not mean it lowers cholesterol, or lowers it significantly. **The type of fiber, the amount of fiber, and the other ingredients all play a role in the ability for the supplement to improve cholesterol levels.**

Gori states his formula "will achieve other well-known benefits of dietary fiber. Among them are included minimizing the possibility of cancer and preventing certain digestive diseases, reducing blood cholesterol and triglycerides [misspelled] to prevent heart diseases, and other benefits that are scientifically known. Of course it is essential to adopt a proper diet, to reduce fats, sugars, and calories, in general and it is helpful to increase one's consumption of fruit, vegetables and nuts." (column 4 lines 6-13) . Applicant, a medical doctor and lipid expert, submits that there is no proof that Gori provides the proper fibers in proper gram amounts to give significant reduction in cholesterol or risk of heart disease. His invention requires a proper diet with reduction of fats, sugar and calories—dietary measures known to help reduce the risk of heart disease alone. **Because Gori ties his invention to these dietary changes, one cannot assume his invention actually does anything more than the diet would do alone.** Applicant

also questions the ability of any human to comply with 10 packets daily. Neither claims HDL or high sensitivity C-reactive protein improvement that applicant claims.

Applicant's benefit of reducing the risk of cardiovascular disease by raising HDL, and lowering high sensitivity C-reactive protein levels provides a new principle of operation not taught in Leitz and Gori .

Applicant's invention's ability to deliver 7 grams of fiber per serving comprising 3 specific fibers once or more daily, is valuable and results in new principal of operation. This clearly proves that applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 53 ARE UNOBVIOUS AS OFFICE ACTION DOES NOT PRESENT A CONVINCING LINE OF REASONING

Applicant respectfully does not see the line of reasoning offered that makes applicant's invention obvious. Applicant cancelled claim 18 and has rewritten it as new claim 53 to more clearly show the novel physical structure that is essential to the method claim.

Applicant respectfully does not see how Leitz and Gori can be combined. They have mutually exclusive features. Even if they are combined, they teach away from the high fiber per serving and teach that mineral and nutrient supplementation is necessary with high fiber. They both teach the need for a balanced formulation consisting of a variety of different fibers. Applicant respectfully does not understand how a combination of Leitz's and Gori's invention make applicant's invention obvious. Leitz and Gori cannot even be combined as they are independent patents that stand on their own and do not suggest combination. Leitz teaches a balanced fiber composition that provides benefits of fiber at **only** modest dose, and Gori teaches a weight control formulation made of balanced fibers supplemented with minerals that is sprinkled on food 10 doses per day. Leitz recommends inert non-toxic carriers to make his invention liquid, but prefers a pill form. Gori teaches a powder that must be sprinkled on foodstuff prior to eating.

Leitz teaches the fruit and vegetable fiber must be 30%- 48.5% of the total fiber, Gori teaches a maximum of 15% fruit and vegetable. These are mutually exclusive ratios.

Neither recommends more than 5 grams per serving as they are concerned fiber above this dosage may be dangerous. Gori teaches the necessity of corn, oat, and wheat bran. Leitz teaches oat, corn, barley, and soy bran. Leitz teaches the **benefits of increased fiber are not without risks and it is critical to keep in mind that very large amounts of fiber interfere with the absorption of other nutrients.** (Column 1 lines 59-68) Gori teaches that **minerals must be supplemented into the formula to replace the minerals that are related or sequestered by the fibers.** (column 2 lines 3-7).

Combining these references would result in a **balanced** fiber formulation containing **at least 12 different fibers and specific fibers would need to be used including oat, corn, barley, wheat, and soy brans, acerola, lemon and carrot pulp, guar, psyllium, cutins and pectin. Also minerals and lubricants, binders and a non-toxic carrier would be added.** Applicant does not understand where it would go from here as Leitz can make a liquid (only if inert carriers are used) or powder but prefers a pill, Gori teaches only a powder that is sprinkled on foodstuff with each meal. Leitz prefers 9 fibers, Gori 7. **Applicant's invention does not require balanced fibers, fruit or vegetable fibers, minerals, wheat, or corn bran fiber, or a non-toxic carrier. Applicant's invention's preferred embodiment is a beverage that delivers ultra-high fiber (at least 7 grams per serving) that does not immediately gel.** Applicant's invention is preferably taken **60-30 minutes prior to eating**, not sprinkled on all foodstuff evenly spaced throughout the day using 10 packets or more.

It is essential that an individual using **Gori's weight control formulation adopt a proper diet, reduce fats, sugar and calories in general.** (Column 4 lines 11-13) . One would have to wonder whether any weight control or **reduction in cholesterol** is coming from his formulation or from the reduction in fats, sugars, and calories that must take place! Applicant's invention requires no special diet or food restriction.

Office action states that it would have been obvious to provide a fibrous composition that would be capable of providing the recommended dosage of 25-40 grams of fiber a day. While it can be argued that current guidelines recommend that level of fiber per day, it is not obvious to **deliver an ultra-high fiber (at least 7 grams per serving) supplement especially when prior art is teaching away from this. Both Leitz and Gori teach away from this—Gori teaches small packets providing 10 or more evenly spaced throughout the day. It is unobvious that ultra high dose fiber per serving (7 grams or greater) can be delivered in a well tolerated non dangerous form.** All prior art teaches against delivery of an ultra-high fiber (at least 7 grams per serving) in one serving. The dangers and side effects of too high a level of fiber per serving are well known in prior art. Applicant further proves this by the NCEP ATP III 2001 guidelines which show that previous research delivered 5-10 grams of fiber per day maximum. (V20-21) **It is also unobvious that ultra high fiber could be delivered without supplemental minerals. Most importantly it is unobvious that 7 grams of fiber or greater could be provided in a beverage form without special processing or inert carriers that does not immediately gel.**

Applicant respectfully feels that no convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art would have been obvious over the combination of Leitz and Gori. Claim 18 was cancelled and rewritten as new claim 53 to clearly show the novel physical features that proves applicant's physical structure and method of delivering ultra-high fiber (at least 7 grams per serving) comprising 3 specific fibers, is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 58 ARE UNOBVIOUS UNDER SEC. 103

Claim 21 has been canceled and rewritten as new independent method claim 58

Claim 21 was rejected under 35 U.S.C 103(a) as being unpatentable over the combination of Leitz (US patent 4,877,627) and Gori (US patent 4,784,861)

Claim 58 states A method of assisting in limiting ingested toxins, carcinogens, and heavy metals in a mammal through reducing absorption and assimilation of toxins and speeding transit out of the body comprising orally administering a nutritional supplement at least one time daily that contains at least 7 grams of fiber per serving and comprises a mixture of guar, oat, psyllium and at least one flavoring agent.

Office action states that under the combination of Leitz and Gori it would have been obvious to make a formulation to bind toxic substances and heavy metals. **Leitz and Gori do not mention this as a benefit of their inventions and therefore could not have been obvious.**

Furthermore, no prior art has developed a way to provide an ultra-high fiber (at least 7 grams per serving) supplement in as easy or quick route of administration. No prior art has taught how an ultra-high fiber (at least 7 grams per serving) supplement could be given safely and without risk or danger to a mammal. No prior art has shown how more than 17 grams of fiber could be safely administered in a matter of minutes to a mammal.

Applicant's novel structure includes guar, oat, and psyllium and a flavoring agent, administered in a serving containing a minimum of 7 grams of fiber.

This novel structure a minimum of 7 grams of fiber, admixed with an ingredient to make an edible food product selected from the group consisting of puddings, snack bars, wafers, and dog bones is also novel. **Gori and Leitz do not teach to make more than 7 grams of fiber per serving and neither teaches to make a pudding, snack bar, wafer or dog bone. Neither teaches to consume an additional liquid with the fiber product to hydrate the consumed fiber.** Applicant's edible food product could be made only with guar, oat, psyllium and a flavoring agent and Gori and Leitz cannot.

Applicant argues that Leitz and Gori cannot be combined. They are both independent patents that do not suggest they can be combined, they are both references that are individually complete, they teach away from a suggested combination, and they cannot be combined based

on their requirements. **Importantly Gori uses the term “consisting of ” in describing his main claim which teaches his formulation is closed ended and CANNOT be combined. Leitz uses the term open-ended term “comprising of” to describe his main claim and that indicates that his composition must include AT LEAST his requirements.** Many of the requirements of Leitz and Gori are mutually exclusive and even though applicant submits they cannot be combined, but even if they were combined, how can it be obvious to know what to combine? Gori teaches oat, corn and **wheat** are a necessity, Leitz does not teach wheat but instead oat, **barley** and corn bran. **Leitz requires 30-48.5% of fiber to come from the fruit and vegetable group, Gori teaches at most 15%.** Gori teaches 14.6% (column 9 table showing fiber content in g. in formulation $\text{cutin and pectin} = 3.0 + 1.9 / 33.4 = 14.6\%$ and % of fruit and vegetable group in column 10 table is $10 + 15 / 100 = 15\%$ fiber from the fruit and vegetable group. **If Gori teaches 15% and Leitz 30-48.5% of fiber must come from the fruit and vegetable group then they teach mutually exclusive information. How can combining mutually exclusive information be obvious?**

Applicant stresses both references teach away from high fiber and though offer their fiber formulation in up to 5 grams per serving, realistically teach 3-3.3 grams maximum fiber per serving (Leitz 1-3 grams and Gori 1-3.3 grams). Applicant wishes to note that the 0.5-5 gram per packet for Gori is his entire formulation of which includes his mineral supplements, the fiber component would be somewhat less.

The following combination of Leitz and Gori would have to contain at least the following based on the two patents:

1. a maximum of 5 grams of fiber per serving
2. at least oat, corn, barley, soy, and wheat brans
3. the cereal component would have to make up 30-48.5% of the final fiber weight,
4. (Leitz) 30-48.5% fiber from the fruit and vegetable group vs. (15% maximum by Gori)
5. lemon, acerola, and carrot pulp
6. 3-40% of the other fibers not from fruit, vegetables, or cereals

7. mineral supplements manganese, selenium, zinc, copper, iron and calcium
8. Must be taken throughout the day sprinkled on foodstuffs.
9. Served as a powder, tablet, chewable tablet, granules, or bulk powder. (A 2 gram fiber per serving beverage is described that must be admixed with liquid food product to ease administration).

Applicant

1. Minimum of 7 grams of fiber per serving
2. At least Oat , guar ,and psyllium and full serving could include just these three fibers
3. No mineral requirements
4. No binders, lubricants, or inert carriers
5. Taken in one or more doses typically 30-60 min before food or instead of food, not with food. **In claim 58, applicant's invention is administered on an as needed basis to bind toxins and speed their elimination from the body.**
6. Preferred is a drink, but could be served in a pudding snack bar, wafer or dog bone

LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR COMBINATION, MUCH LESS THE MANNER PROPOSED

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.... *Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed

invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove **all** fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently.** Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through

creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant's because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

"That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention."

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P.

706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra , a “factual basis to support his conclusion that it would have been obvious” to make the combination.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TEACH AWAY FROM THE SUGGESTED COMBINATION

Leitz and Gori are two independent patents that teach how to make their individual inventions. They use different approaches and have different main functions. Leitz teaches a balanced fiber formulation to provide a beneficial total dietary fiber balance **modeled after the basic food group approach**. Gori teaches primarily a balanced fiber composition for weight control. They both use a variety of fibers but recommend different percentages of certain classes of fibers. Leitz recommends 30-48.5% fiber from fruit and vegetable group, whereas Gori only 15%. Gori stresses the importance of the cereal group requiring corn, oat and wheat bran, it makes up 55% of his formulation. Gori stresses the importance of **wheat** and makes it essential to his formulation. Leitz recommends corn, oat and **barley** and **does not recommend wheat**. **Leitz teaches that the fibers he picked were carefully selected to provide the desired nutritional benefit. Gori requires specific minerals, Leitz does not.** Leitz requires acerola, carrot and lemon pulp, none of which are taught by Gori. Gori must be sprinkled on foodstuffs throughout the day, this is not required by Leitz. Applicant respectfully submits that these are different patents that require different essential elements, and therefore, teach a difference of opinion. Applicant respectfully does not understand how the differences could be brought into combination. Applicant respectfully submits because they teach away from being combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES BECAUSE THEY ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and certain percentages to make their invention. They are different. Applicant does not understand how two mutually exclusive elements can be combined. Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat, Leitz teaches barley. Leitz does not require minerals, Gori requires specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises** 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group **consisting of** acerola, carrot, or lemon. Gori uses the word “consisting of” in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims.** Gori requires a powder to be sprinkled on foodstuffs throughout the day, Leitz does not. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their different requirements. Applicant’s novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE MUTUALLY EXCLUSIVE PATHS

Leitz and Gori cannot legally be combined because they take mutually exclusive paths to reach different solutions to a problem, therefore by implication each teaches away from combining itself with the other. Both teach a fiber composition to provide a fiber balance to mammal. They however teach different requirements are necessary to provide this balanced fiber. Leitz models his fiber composition after the dietary fiber found in the basic food group approach to nutrition, **Gori’s substance of his invention is designed to restore the natural fibers that modern food technology is know to remove from the processed foods (column 3 lines 40-44). Gori teaches to use brans with other gut influencing substances to formulate a weight control substance.** Leitz teaches the balance of fiber based on 3 groups and a variety of fibers within each group. Gori’s formulation must be added to all foodstuffs throughout the day. Leitz does not teach this.

While both Leitz and Gori attempt to provide balanced fiber to a mammal, they use different approaches and this results in different functions. Leitz does not teach weight control, Gori does. Leitz and Gori should not be combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES HAVE CLAIMED FEATURES LACKING

Even if Leitz and Gori could be combined certain claims would not be met. For example, **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Leitz teaches administration 1-4 times per day. Gori requires his invention to be sprinkled on food stuffs throughout the day. Gori requires wheat bran, Leitz teaches barley bran. Gori teaches all fibers are different and cannot be interchanged.** Applicant submits that Leitz and Gori would not meet all their claims if combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED DUE TO THE MULTIPLICITY OF STEPS REQUIRED

The combination requires a series of requirements set forth in the detailed descriptions and claims that makes trying to combine the two very difficult and not obvious. One would have to add wheat to Leitz and still obey the proper cereal ratio. The only fruit that Gori allows is pectin and cutin, and this goes against Leitz carefully selected acerola, lemon, and carrot pulp that provides the fiber balance he teaches. The end result would have to be powder that is sprinkled on foodstuffs throughout the day as Gori teaches. **One would not know how to resolve the difference between the fruit and vegetable total fiber ratio that is mutually exclusive, Leitz being 30-48.5% of total fiber, and Gori being 15% or less. Leitz teaches 30-48.5% from the cereal group, Gori 55%.** Great difficulty exists in trying to obey all the requirements of both

references with respect to ratios and the great variety of fibers both teach. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

**EVEN IF LEITZ AND GORI WERE TO BE COMBINED IN THE MANNER
PROPOSED THE PROPOSED COMBINATION WOULD NOT SHOW ALL OF THE
NOVEL FEATURES OF CLAIM 58**

However, even if the combination of Leitz and Gori were legally justified, claim 58 would still have novel (and unobvious) physical features over the proposed combination. In other words, applicant's invention, as defined by claim 58 comprises much more than merely using oat, guar and psyllium.

Applicant's invention uses specific fibers with specific physical characteristics and properties (mesh sizes, viscosities, fat and water absorption). Applicant's novel physical structure allows **7 or more grams of fiber per serving** to be admixed with a liquid to create a beverage that does not immediately gel. Combining the variety of fibers in Leitz and Gori would immediately gel—the expected result. Combining Leitz and Gori does not produce weight loss as Leitz does not teach how weight loss could occur, and although Gori teaches weight control without causing satiety, his formula **still requires reduction of fats, sugar and calories—a diet** itself that can give weight loss. Applicant's invention produces dramatic weight loss in major part due to the satiety that it causes before the meal and for several hours afterward. Gori teaches weight control by the use of 3 different brans that modulate food moving in and out of the stomach. Applicant teaches weight loss by creating satiety with fiber before the meal, so that the mammal feels full at time of the meal, and eats less. This reduction in calories consumed results in easy weight loss that does not require food avoidance or exercise. **Creating satiety prior to mealtime or snack time is an unexpected result. Having satiety that lasts for several hours after consuming applicant's invention is a new and unexpected result. Being able to lose weight without food avoidance, dieting, or exercise is a new and unexpected result.**

The Novel Physical Feature Of Claim 58 Produces New And Unexpected Results And Hence Are Unobvious And Patentable Over These References Under § 103.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 DUE TO IMPROPER COMBINATION OF REFERENCES THAT DO NOT SUGGEST COMBINATION.

Applicant respectfully submits that Leitz and Gori should not be combined.

Leitz and Gori are independent, stand alone references. They do not contain any suggestion whether expressed or implied that they should be combined in any one manner or in any manner at all. It cannot be obvious to combine any two references that do not suggest combination in any manner. It cannot be obvious to combine two references that have mutually exclusive parts.

Applicant is unobvious over Leitz and Gori under Sec. 103 due to an unsuggested combination of references and applicant's novel structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 DUE TO IMPROPER COMBINATION OF REFERENCES THAT ARE INDIVIDUALLY COMPLETE.

Applicant respectfully submits that Leitz and Gori should not be combined.

Leitz and Gori are individual references that are complete and functional to themselves. There is no reason to use parts from, or add, or substitute parts to any reference. Leitz and Gori are stand alone references and should remain stand alone references.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant is unobvious over Leitz and Gori under Sec. 103 due to improper combination of two individually complete references and applicant's novel structure. .

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 DUE TO IMPROPER COMBINATION OF REFERENCES THAT TAKE DIFFERENT APPROACHES.

Applicant respectfully submits that Leitz and Gori should not be combined. Leitz and Gori take different approaches so it cannot be obvious to combine them.

Leitz is a **balanced fiber composition** whose object is to provide an appropriate balance of fibers to an organism. Gori is a **weight control formulation** that uses a balance of fibers. The individual fibers, and the specific ratios of fibers, and the method of delivery of fibers are different for the two references. They teach different approaches. **Leitz teaches to balance the fibers based on the basic food group approach to sound nutrition. Gori teaches to use brans in conjunction with other gut influencing substances and to accommodate the utilization of fiber sources by incorporating minerals to replace the minerals that were related or sequestered by fibers.**

These are very different approaches and since they teach away from each other it is not logical to combine them.

Applicant teaches a fiber supplement that does NOT require balance and delivers at least 7 grams of fiber per serving.

Applicant is unobvious over Leitz and Gori under Sec. 103 due to improper combination of two references that take different approaches and applicant's novel structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 DUE TO IMPROPER COMBINATION OF REFERENCES THAT TEACHES AWAY FROM SUGGESTED COMBINATION.

Applicant respectfully submits that Leitz and Gori should not be combined. Leitz and Gori teach away from any suggested combination.

Leitz is a **balanced fiber composition** whose object is to provide an appropriate balance of fibers to an organism. Gori is a **weight control formulation** that uses a balance of fibers. The individual fibers, and the specific ratios of fibers, and the method of delivery of fibers are different for the two references. Gori must be sprinkled on all foodstuffs throughout the day, Leitz prefers a tablet, chewable tablet, or bulk fiber that can be made into a beverage. They teach different approaches. Leitz teaches to balance the fibers based on the **basic food group** approach to sound nutrition. Leitz requires 30-48.5% of the total fiber to come from the fruit and vegetable group. Gori teaches at most 15% from the fruit and vegetable group. Gori teaches to **use brans in conjunction with other gut influencing** substances and to accommodate the utilization of fiber sources by **incorporating minerals** to replace the minerals that were related or sequestered by fibers. Gori teaches **wheat** oat and corn bran, Leitz teaches corn, oat, **soy** and **barley bran** are best. Gori teaches minerals are a necessary part of the formulation, Leitz does not. **Leitz teaches the fiber weight from the fruit and vegetable group must be 30-48.5%, Gori teaches a maximum of 15%.** These fiber ratios are mutually exclusive. **How can it be obvious to know**

how much fruit and vegetable fiber to use in a formulation when faced with mutually exclusive values?

These are very different approaches and since they teach away from each other it is not logical to combine them.

Applicant teaches a fiber supplement that does NOT require balance and delivers at least 7 grams of fiber per serving. Both references teach away from using more than 5 grams of fiber per serving due to dangers and risks and prefer to actually use much less (1-3 grams of fiber per serving)..

Applicant is unobvious over Leitz and Gori under Sec. 103 due to improper combination of two references that teach away from suggested combination and applicant's novel structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 DUE TO IMPROPER COMBINATION OF REFERENCES THAT ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and specific percentages of each fiber to make their invention and their novelty. They are different. Applicant does not understand how two mutually exclusive elements can be combined. **Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%.** Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat, Leitz teaches barley and soy bran. Leitz does not require minerals, Gori requires very specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises** 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group **consisting of** acerola, carrot, or lemon. Gori uses the word "consisting of" in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable**

group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Gori requires a powder to be sprinkled on foodstuffs throughout the day (10 times per day), Leitz does not and teaches administration 1-4 times per day. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their specific requirements and combine them.. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

Applicant teaches a fiber supplement that does NOT require balance and delivers at least 7 grams of fiber per serving. Both references teach away from using more than 5 grams of fiber per serving due to dangers and risks and prefer to actually use much less (1-3 grams of fiber per serving).

Applicant is unobvious over Leitz and Gori under Sec. 103 due to impossible combination of two references that logically cannot be combined and even if combined would not have applicant's novel physical structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 BECAUSE COMBINATION OF REFERENCES WOULD RESULT IN AN INOPERATIVE COMBINATION

Leitz and Gori cannot be combined, but if combined would be an inoperative combination.

Gori's weight formulation requires the formula to be sprinkled on all foodstuffs throughout the day (average 1 packet 10 times per day). Leitz prefers a tablet, chew tablet, or bulk form powder that can be used as a beverage. Leitz does teach his composition could be sprinkled on a salad or breakfast food as a powder or granule, but teaches administration is only **1-4 times** per day. (Column 5 lines 40-64). Gori does not teach any administration form other than packets sprinkled on **all foodstuffs throughout the day**, on average 1 packet **10 times per day**. Leitz preferred tablet, chewable tablet, or beverage is not operative with Gori insistence on sprinkling on all foodstuffs. **There is no proof that the non toxic carriers typically associated with Leitz**

would not bind to the minerals of Gori and prevent their ultimate absorption. Applicant submits that Gori teaches all about the importance of brans and how they provide different functions, yet does not suggest barley bran found in Leitz. Applicant submits that there may be a problem with combining barley bran with oat, corn and wheat and may inactivate or prevent absorption, or even prevent use of sprinkling of Gori's desired brans.

Applicant teaches a fiber supplement that does NOT require balance and delivers at least 7 grams of fiber per serving. Both references teach away from using more than 5 grams of fiber per serving and prefer to use much less 1-3 grams.

Applicant is unobvious over Leitz and Gori under Sec. 103 due to improper combination of two references that cannot be combined, but even if combined result in an inoperative combination and applicant's novel structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 BECAUSE REFERENCES CANNOT BE LEGALLY COMBINED BECAUSE THEY TAKE MUTUALLY EXCLUSIVE PATHS

Leitz is a **balanced fiber composition** whose object is to provide an appropriate balance of fibers to an organism. Gori is a **weight control formulation** that uses a balance of fibers but **teaches the importance of using brans in conjunction with other gut influencing substances.** Gori teaches all fibers are different, unequal and cannot simply be exchanged for one another. Both Leitz and Gori teach the importance of specific individual fibers, specific ratios of those fibers, and a specific method of delivery of those fibers. The two references are very different. Gori must be sprinkled on all foodstuffs throughout the day, Leitz prefers a tablet, chewable tablet, or bulk fiber that can be made into a beverage. They teach different approaches. Leitz teaches to balance the fibers based on the **basic food group** approach to sound nutrition. Leitz requires 30-48.5% of the total fiber to come from the fruit and vegetable group. Gori teaches at most 15% from the fruit and vegetable group. **Leitz teaches 30-48.5% from the cereal group,**

Gori 55%. Gori teaches to **use brans in conjunction with other gut influencing** substances and to accommodate the utilization of fiber sources by **incorporating minerals** to replace the minerals that were related or sequestered by fibers. Gori teaches **wheat** oat and corn bran, Leitz teaches corn, oat and **barley bran** are best. Gori teaches minerals are a necessary part of the formulation, Leitz does not. Gori teaches weight control, and Leitz does not.

Applicant submits that each reference teaches a mutually exclusive path to make their individual formulation so they cannot legally or logically be combined. Leitz and Gori teach different solutions to the **same and different** problems. Leitz teaches to **provide a balance of fiber** through using 3 groups of fibers in a specific ratio based on the basic food group approach to sound nutrition. Gori teaches a **balance of fiber** through using different fibers in a different ratio and the importance of oat, corn and wheat brans along with supplemental minerals. Gori teaches that fibers are not to be considered equal to each other and each reference requires specific fibers, of which some are different and the ratios of fiber groups are different. The two references also teach solutions to **2 different problems**. Gori teaches weight control, Leitz does not.

Applicant teaches a fiber supplement that does NOT require balance and delivers at least 7 grams of fiber per serving. Both references teach away from using more than 5 grams of fiber per serving and prefer to use much less 1-3 grams.

Applicant is unobvious over Leitz and Gori under Sec. 103 due to illegal and illogical combination of two references that cannot be combined because they take mutually exclusive paths and due to applicant's novel structure.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103 BECAUSE THE COMBINATION OF LEITZ AND GORI LACKS CLAIMED FEATURES OF APPLICANT'S NOVEL STRUCTURE

Applicant teaches a fiber supplement that does NOT require a balance of fibers and delivers at least 7 grams of fiber per serving. Applicant is also able to deliver the fiber in a liquid beverage that does not immediately gel. In a preferred embodiment applicant teaches to make a zero calorie beverage containing at least 7 grams of fiber per serving that does not immediately gel. Both references teach away from using more than 5 grams of fiber per serving and prefer to use much less, preferably 1-3 grams of fiber. Neither reference individually or in combination shows how a zero calorie beverage can be made, nor a beverage containing at least 7 grams of fiber that does not immediately gel. (Leitz teaches his fiber formulation can be added to a liquid food product but recommends only 2 grams of fiber which is less than his 1-3 grams of fiber for his other embodiments, and much less than the 5 gram per serving maximum. Applicant submits that Leitz reduces the fiber to 2 grams because of problems with gelling at higher doses. Applicant's novel physical structure is novel because applicant can deliver at least 7 grams of fiber per serving with as few as 3 fibers, the references use 7-9 fibers and if combined would use a minimum of 12 fibers.

Even if combined, applicant's invention has features that a combination of Leitz and Gori would not have.

Applicant is unobvious over Leitz and Gori under Sec. 103 novel physical structure and the fact that a combination of Leitz and Gori still does not have several features of applicant's novel structure.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES ARE INDIVIDUALLY COMPLETE

Applicant submits that Leitz and Gori should not be combined because each reference represents a complete and functional patent. Therefore, there is no reason to add or substitute parts of a patent with another patent.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant's novel physical structure is unobvious and clears Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL STRUCTURE OF CLAIM 58 IS UNOBVIOUS OVER LEITZ AND GORI UNDER SEC. 103

Leitz and Gori do not teach that their inventions detoxify substances. Both teach away from using more than 5 grams of fiber per serving and actually prefer at most 3.3 grams. It is unobvious that applicant provides an ultra-high fiber (at least 7 grams per serving) supplement and a method for assisting in limiting ingested toxins, carcinogens and heavy metals. Applicant submits, how can it be obvious if neither reference teaches it?

Applicant's novel structure and method of assisting in limiting ingested toxins is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO LACK OF IMPLEMENTATION

If applicant's invention was in fact obvious, because of its advantages, those skilled in the art surely would have implemented it by now. The fact that those skilled in the art have not implemented applicant's invention despite its great advantages, indicates that it is not obvious. Prior art has used oat, guar and psyllium fibers, but no prior art has taught how to use fibers with

specific physical characteristics and properties so as to create a minimum of 7 grams of fiber per serving that could be easily taken in one or more daily doses and assists in limiting ingested toxins and detoxifies toxic substances.

If using 7 or more grams of fiber per serving was obvious, Leitz and Gori would have surely taught that in their patent. The fact that they taught 5 grams or less per serving indicates applicant's invention was unobvious. Even 5 grams was too high for both, and that is why they prefer a 1-3.3 gram per serving of fiber. Furthermore, Gori teaches to give 10 packets 10 times per day, proving that he does not want to give too much fiber at one serving. While prior art has used guar, oat, and psyllium none has combined the three fibers in an easy to administer 7 gram of fiber (minimum) per serving supplement and taught a method of assisting in limiting ingested toxins and detoxifying toxic substances. Applicant submits many advantages to his novel structure. Applicant provides a method of delivering ultra-high fiber (at least 7 grams per serving) easily and safely and with no significant side effects. The majority of applicant's users are consuming 17 grams of fiber daily. Applicant makes administration of more than 14 to 28 grams of fiber equally as easy.

The lack of implementation of the applicant's invention along with its novel physical structure clearly proves applicant's novel structure is unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIM 58 ARE UNOBVIOUS DUE TO A NEW PRINCIPLE OF OPERATION

The new principle of operation includes serving at least 7 grams of fiber per serving. By serving more fiber per dose, more success can be achieved in limiting absorption of toxins and better detoxification can take place. Leitz and Gori teach away from high fiber and do not teach that their invention can be used for detoxification.

Applicant is unaware of any prior art teaching detoxification with 7 grams of fiber per serving administered at least once daily. **Applicant's ease of administration of fiber in ultra-high fiber doses (at least 7 grams per serving), allows for more rapid and more superior detoxification as multiple servings of more than 7 grams can be administered in short periods of time.** (In one of applicant's preferred embodiments a beverage of 17 grams of fiber is administered in one serving based on a 2 scoop per serving basis . There is no reason why these beverages could not be given almost continuously to speed detoxification and elimination of the ingested toxins.

The novel physical features of claim 58 provides a new principle of operation that is not found in Leitz and Gori, and is therefore unobvious under Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO UNAPPRECIATED ADVANTAGE

Applicant's novel structure allows for at least 7 grams of fiber per serving to be administered to a mammal. The ease of administration allows for several servings to be given over a short period of time, thus allowing for very high doses of fiber to be administered quickly. This provides a great advantage to a mammal that has ingested a toxin. **Higher doses of fiber allow for greater binding to the toxin, and more speedy elimination through the digestive tract. These two factors alone would greatly inhibit the absorption of toxin into the body of the mammal.** Applicant provides in claim 63 the ability to provide additional ingredients that would serve to further detoxify toxins. Many plant and synthetic sources of detoxifying agents exist that could be added.

Leitz and Gori do not teach detoxification with their inventions. It cannot be obvious to look at two references that do not teach something and then combine them and say it is obvious they teach something new. Even if it is known in prior art that fiber can detoxify, applicant is unaware of any reference that teaches delivery of ultra-high fiber (at least 7 grams per serving) and the superior advantages of binding and elimination.

The novel physical features of claim 63 provide an unappreciated advantage that is not found in Leitz and Gori, and is therefore unobvious under Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO AN UNRECOGNIZED PROBLEM

Leitz and Gori do not teach that fiber can be used to detoxify ingested toxins, prior art does not teach the detoxifying benefits of applicant's novel physical structure comprising guar, oat, and psyllium and at least one flavoring agent administered in an at least 7 grams of fiber per serving. The problem of ingested toxins and how to minimize their toxicity is an unrecognized problem in both Leitz and Gori. Since Leitz and Gori do not make mention of ingested toxins, it would be unobvious that individually or in combination that Leitz and Gori could offer a solution to an unrecognized problem. The novel physical features of applicant's invention is thus unobvious over Leitz and Gori under Sec. 103.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO AN OMISSION OF ONE OR MORE ELEMENTS

As explained above Leitz and Gori require 7-9 fibers, very specific fibers and specific percentages or ratios of certain fibers or fiber classes. Both require a balance of fibers though they define fiber balance differently. Gori requires minerals as part of his formulation.

Applicant requires only 3 fibers, does not require a fiber balance, and does not require acerola, lemon carrot, corn, barley, wheat, soy or specific minerals, which are required by the combination of Leitz and Gori. Applicant does not sprinkle on all foodstuffs during the day, rather serves invention 30-60 minutes prior to a meal.

Applicant's novel structure omits many elements of Leitz, Gori and the combination of the two. **Applicant omits many fibers, the specific ratios, the specific minerals, and the inert carriers.** Applicant's novel structure provides superior and new health benefits.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to omission of one or more elements.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO LACK OF IMPLEMENTATION

Applicant's novel structure and method of limiting ingested toxins, carcinogens, and heavy metals in a mammal through reducing absorption and assimilation of toxins and speeding their elimination is unobvious as it has not been implemented previously. Applicant is a physician who is board certified in internal medicine and has had considerable emergency room experience. Applicant is unaware of a commercial fiber product that can limit ingested toxins, carcinogens, and heavy metals.

If the invention was in fact obvious, surely those skilled in the art would have implemented it by now. The fact that those skilled in the art have not implemented such an invention, despite its great advantages, indicates that it is not obvious.

Leitz and Gori do not teach anything about limiting ingested toxins, carcinogens, and heavy metals.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to lack of implementation.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO SOLVING OF A LONG-FELT AND UNSOLVED NEED

Thousands of emergency room visits per year are due to accidental ingestion of toxins, and dangerous substances. **Typical treatment involves administering charcoal to neutralize some toxins, syrup of ipecac to induce vomiting and stomach lavage (stomach pump) whereby the contents of the stomach are removed with suction. Ingested toxins that have been ingested for more than 30 minutes may have left the stomach and cannot be suctioned out. Certain toxins should not be vomited out, as their elimination through the esophagus can further damage the esophageal lining. There has been a long-felt unsolved need to have alternative methods to help limit the toxicity of ingested toxins and poisons.**

Applicant's invention allows for delivery of ultra-high fiber (at least 7 grams per serving) oral dosage that can assist in limiting absorption and speeding elimination of ingested dangerous substances. The fact that several doses or servings each containing at least 7 grams of fiber per serving can be administered quickly and conveniently allows for a massive amount of fiber to be ingested. Applicant's fiber can bind to ingested toxins and prevent absorption and can speed elimination through the digestive tract to further limit toxin exposure to the mammal. **Especially advantageous are the cases in which the toxin has been ingested for at least 30 minutes. Applicant's fiber supplement can be administered in large doses that bind to the toxin and push the toxin through the intestine, thus limiting a toxin's ability to be absorbed. Repeated dosing of fiber, one after the other of applicant's invention could push the toxins out quickly. Applicant's invention can further be enhanced to limit toxins by admixing in known detoxifying substances that are from plants, or synthetically made.**

Leitz and Gori do not teach how to limit toxin exposure through their invention.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to providing a solution to a long-felt and unsolved need.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO CONTRARIAN INVENTION

Applicant's is contrarian to Leitz, Gori, and the combination of the two. Leitz and Gori teach that a balance of fibers is necessary and that 5 grams of fiber or less per serving is necessary. Both prefer much lower doses, such as 1-3 grams of fiber per serving.

Applicant teaches that no balance is necessary, and that as few as 3 specific fibers are needed. Applicant teaches an ultra-high fiber (at least 7 grams per serving) dosage. This novel physical structure allows for new and superior health benefits including assisting in the limiting of absorption of toxins and speeding their elimination. Applicant is a contrarian invention to Leitz, Gori and any combination of the two. Applicant's novel structure allows for the benefits of claim 58.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to the fact it is a contrarian invention .

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO LEITZ AND GORI BEING PAPER PATENTS

Applicant respectfully believes that Leitz and Gori are paper patents. Both patents are more than 10 years old and applicant is unaware of any commercial products existing. Because these two are paper patents they should be construed more narrowly. Leitz and Gori do not teach that their inventions can even detoxify substances. Applicant is a commercially successful product that has novel structure over both Leitz, Gori, and their combination.

Applicant's novel structure is unobvious over Leitz and Gori under Sec. 103 due to Leitz and Gori being paper patents.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO NEW PRINCIPLES OF OPERATION

Leitz and Gori do not teach that fiber can be used to detoxify ingested toxins, prior art does not teach the detoxifying benefits of applicant's novel physical structure comprising guar, oat, and psyllium and at least one flavoring agent administered in an at least once daily and having a minimum of 7 grams of fiber per serving.

Applicant provides at least 2 new principles of operation. One principle of operation is the fact that applicant has ability to deliver very high amounts of fiber in a short period of time which allows for superior binding and elimination of toxins. Applicant's novel structure allows for an ultra-high fiber dose with at least 7 grams per serving, to be given repeatedly in a short period of time. This makes administration of 17 to more than 50 grams easily done in a matter of minutes to an hour. This dosing can then be repeated as often as necessary to guarantee elimination of the toxins. References teach 1-3 grams of fiber is preferred and that high doses of fiber are dangerous. Applicant teaches a new principle of operation that high fiber delivered over a short period of time offers superior toxin binding and elimination over small and modest fiber delivery.

Applicant also provides a new principle of operation in the fact that a beverage containing at least 7 grams of fiber per serving can be made that does not immediately gel. This allows for both ease of use, and allows for increased propulsion or elimination of the toxin as the fibers are well hydrated and gain weight producing a mass effect further pushing undigested material through the colon. Applicant also offers semisolid and solid delivery of fiber where by pudding, wafers, snack bars or dog bones could be consumed and followed with sufficient liquid to fully hydrate the fiber.

Applicant is contrary to Leitz, Gori, and the combination of the two as they teach fiber balance, and applicant does not. Applicant's new principle of operation is that an ultra-high fiber (at least

7 grams per serving) dosage can be given that helps bind and eliminate toxins by its novel structure requiring only 3 fibers. Applicant teaches specific fibers are necessary but balance is not a requirement.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to applicant's new principles of operation.

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO SOLVING A DIFFERENT PROBLEM

Applicant's novel physical structure is unobvious as it solves a different problem than Leitz, Gori, and the combination of the two.

Leitz and Gori do not teach that they can limit absorption or speed elimination of toxins. Applicant does. Therefore, applicant solves a different problem than the references and therefore must be unobvious.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to applicant's solving a different problem than Leitz and Gori .

THE NOVEL PHYSICAL FEATURES OF CLAIMS 58 ARE UNOBVIOUS DUE TO LACK OF CONVINCING REASONING

Applicant respectfully submits that there is no convincing reasoning that the references made applicant's claim of limiting toxin absorption and speeding elimination obvious. The references did not even deal with toxins, detoxification or how to speed elimination. Applicant submits that if 2 individual stand alone patents do not discuss a solution to a problem, it cannot be obvious that combining them results in a solution to the problem.

Applicant's novel structure is unobvious due over Leitz and Gori under Sec. 103 due to no convincing reasoning .

Since all the applicant's independent claims recite novel and unobvious subject matter over Leitz and Gori, applicant submits that these claims should be allowed, which action applicant respectfully solicits.

THE DEPENDENT CLAIMS ARE A FORTIORI PATENTABLE

Since independent claims 24, 42, 45, 53, and 58 shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 26-36, 43-44, 46-47, 54-57, and 59-62 are a fortiori patentable over Leitz and Gori

For examiner's clarification:

Dependent claims 3, 5, 6, 10, have been cancelled and rewritten as new claims 26, 31, 32, and 36.

Dependent claim 2 has been cancelled and rewritten as new dependent claim 25

Dependent claim 3 has been cancelled and has been rewritten as new claim 27

Dependent claim 4 has been cancelled and has been rewritten as new claim 28

Dependent claim 5 has been cancelled and has been rewritten as new claim 30

Dependent claim 6 has been cancelled and has been rewritten as new claim 31

Dependent claim 7 has been cancelled and has been rewritten as new claim 32

Dependent claim 8 has been cancelled and has been rewritten as new claim 33

Dependent claim 9 has been cancelled and has been rewritten as new claim 34

Dependent claim 10 has been cancelled and has been rewritten as new claim 35

Dependent claim 11 has been cancelled and has been rewritten as new dependent claims 26 & 29.

Dependent claim 36 is a new claim .

Since independent claim 16 was cancelled and rewritten as new claim 42 & 45 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claim 17 was cancelled and rewritten as new dependent claims 43-44, 46-47 and are a fortiori patentable over Leitz and Gori.

Since independent claim 18 was cancelled and rewritten as new claim 53 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 54-57 are a fortiori patentable over Leitz and Gori

Since independent claim 21 was cancelled and rewritten as new claim 58 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 59-62 are a fortiori patentable over Leitz and Gori

Since independent claims 24, 42, 45, 53, and 58 are shown to recite novel and unobvious subject matter over Leitz, all the dependent claims 26-36, 43-44, 46-47, 54-57, and 59-62 listed above are a fortiori patentable over Leitz and Gori.

Moreover applicant submits that the following dependent claims 26-36, 43-44, 46-47, 54-57, and 59-62 are independently patentable over Leitz and Gori for the following reasons.

Claim 25 provides specific gram amounts for the guar, oat, and psyllium that are much greater in gram weight than Leitz and Gori. Leitz and Gori's **maximum** combined weight of guar, oat and psyllium is less than 1 gram, applicant's **minimum** combined weight of the same three fibers is 2.5 grams. This proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 26 shows admixing at least one ingredient allows for a liquid, semisolid or solid. Leitz teaches tablets, chew tablets, bulk powder, granules, and a 2 gram fiber beverage mixed with liquid food stuffs. Gori teaches only a powder that is sprinkled on food stuffs. Leitz and Gori show a maximum of 5 grams of fiber per serving but prefer 1-3 grams. Neither shows a semisolid administration form. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 27 teaches additional fibers that can be added and specifies them by their solubility. Leitz teaches fibers based on 3 groups, vegetable and fruit, cereal, and other. Gori teaches that a variety of bran fibers are necessary to control flow of food in and out of the stomach. Applicant does not use these groups and instead uses fibers based on solubility. These provide different means of classifying the fibers. Applicant does not require any further fibers, but additional fibers can be added. Applicant does not require the ratios of fiber groups which are a necessity with Leitz. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 28 teaches how to make a beverage and a zero calorie beverage. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 29 teaches how to make a semisolid or solid especially a pudding, snack bar, wafer or dog bone. Leitz does not teach these comestibles, instead teaches a tablet, chew tablet, and granules.

Gori teaches only powder to sprinkle on food stuffs. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103..

Claim 30 further defines the flavoring agents that are a necessary part of applicant's supplement. Leitz does not require a flavoring agent but could add one. Gori does not mention flavoring agents. Leitz is associated with a binder, inert carrier or lubricant, applicant is not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 31 teaches that additional ingredients that improve visual or organoleptic appeal can be added. Leitz does not discuss thickening agents, thinning agents, or emulsifiers. Leitz discusses need for a binder, lubricant, or inert carrier perhaps to hold the tablet together. Gori does not teach thickening agents, thinning agents, or emulsifiers. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 32 teaches an antioxidant can be added. Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 33 teaches a tea can be added, Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 34 teaches vitamins, minerals, coenzymes, electrolytes etc. can be added, Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 35 teaches one caloric ingredient can be added including carbohydrates, fats, and proteins. Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 36 shows a preferred alternate embodiment with green tea, multianthocyanadins, folic acid, pyridoxine, locust bean gum, pectin, and at least one sweetener and flavoring agent. Leitz and Gori do not teach this structure, and instead teach a balanced structure with 7-9 fibers. . This shows very different structure than Leitz and Gori. Leitz and Gori teach very specific fibers and locust bean gum is not one of them. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 43 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 44 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 46 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 47 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 54 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 55 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact

that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 56 teaches how to make a beverage and a **zero calorie beverage**. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 57 further describes the method of making a semisolid or solid comestible and the additional step of consuming a liquid to hydrate the fiber. Leitz and Gori do not teach a pudding, wafer, snack bar, or dog bone. Neither teaches to consume sufficient liquid to hydrate the consumed fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 59 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 60 shows that numerous additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and

the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 61 teaches how to make a beverage and a **zero calorie beverage**. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 62 further describes the method of making a semisolid or solid comestible and the additional step of consuming a liquid to hydrate the fiber. Leitz and Gori do not teach a pudding, wafer, snack bar, or dog bone. **Neither teaches to consume sufficient liquid to hydrate the consumed fiber.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Therefore applicant submits that dependent claims 26-36,43-44, 46-47,54-57, and 59-62 are independently patentable over Leitz and Gori and should a fortiori be allowed.

THE ALLOWABLE CLAIMS

The office action stated that independent claim 13 and dependent claims 14 and 15 were allowable under 35 U.S.C 102(b) and 103 (a).

Claim 13 was cancelled and rewritten as new claim 37 to more particularly define the method and the benefits provided by the novel structure.

Claim 37 shows a method of improving the health of a mammal comprising orally administering a nutritional supplement containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent to a mammal at least one time daily whereby consumption results in at least one health benefit including increasing fiber intake, promoting weight loss, enhancing nutrition, reducing the risk of developing and aiding in the treatment of diet-related diseases including insulin resistance, glucose intolerance, diabetes, hypertension, osteoporosis, sleep apnea, constipation, diverticulosis, hemorrhoids, irritable bowel syndrome, and diet-related cancers, aiding in the prevention and treatment of metabolic syndrome, reducing the risk of developing and aiding in the treatment of cardiovascular diseases, improving serum cholesterol, lipoproteins, lipids, triglycerides, and homocysteine, reducing cardiovascular inflammation and serum high sensitivity C-reactive protein levels, and assisting in limiting absorption of ingested toxins, carcinogens, and heavy metals, and speeding their transit out of the body.

Examiner had suggested that method claims show limitations of who is the subject of administration, and steps of the method. Applicant has complied.

Claim 37 now shows that the **limitation** of administering the nutritional supplement to a **mammal** and the **limitation** of “**having a minimum of 7 grams of fiber**” has been added. The **limitation** of administering the nutritional supplement **at least one time daily** and the **limitation** of **at least one health benefit** have also been added.

Under diet related diseases, the following has been added to more clearly define the health benefits: **including insulin resistance, glucose intolerance, diabetes, hypertension, osteoporosis, sleep apnea, constipation, diverticulosis, hemorrhoids, irritable bowel**

syndrome, and diet-related cancers, aiding in the prevention and treatment of metabolic syndrome. This is not new matter and is covered in original application.

Dependent claim 14 has been cancelled and rewritten as dependent claims 38 and 39.

Since independent claim 37 is shown to recite novel and unobvious subject matter over Leitz, the dependent claims 38, 39, 40, and 41 are a fortiori patentable over Leitz.

Moreover applicant submits that the following dependent claims are independently patentable over Leitz for the following reasons

Claim 38 shows: The method according to claim 37, in which at least one edible liquid selected from the group of liquids consisting of zero calorie and calorie containing liquids is admixed to said nutritional supplement of claim 37 in sufficient quantity to create at least an 8 ounce beverage selected from the group consisting of zero calorie and calorie containing beverages.

Gori does not teach how to make a beverage. Leitz teaches as a beverage that is only 2 grams of fiber per serving and must be admixed in liquid food product and have an inert non toxic carrier to ease administration. Applicant's novel physical structure includes 7 grams of fiber per serving, guar, oat, and psyllium, and at least one flavoring agent. Applicant can make a ZERO calorie drink. Leitz requires 9 fibers, specific fibers that create his novel balance, specific ratios of the specific fibers, an inert carrier and can create a beverage that is **only 2 grams of fiber per serving** and requires a liquid food product. Applicant does not require a liquid food product or an inert carrier and places the limitation of requiring **at least an 8 ounce beverage** be created.

Claim 38 teaches how to make a beverage and a **zero calorie beverage**. Gori does not teach a beverage. Leitz teaches only a **2 gram beverage** that is admixed with a liquid food product. Applicant has **7 grams of fiber per serving** and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the**

limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage. Gori teaches only to make a powder sprinkled on food stuffs, not a beverage. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 39 shows :

The method according to claim 37, further comprising:

(a) admixing at least one ingredient to form an edible food product selected from the group of solid and semisolid food products consisting of puddings, snack bars, wafers, and dog bones which is consumed at least one time daily, and

(b) said edible food product to be accompanied by consumption of sufficient quantity of at least one edible liquid selected from the group of liquids consisting of zero calorie and calorie containing liquids to further hydrate the consumed fiber.

Claim 39 further describes the method of **making a semisolid or solid comestible** and the **additional step of consuming a liquid to hydrate the fiber. Leitz and Gori do not teach a pudding, wafer, snack bar, or dog bone.** Neither provides a method claim. **Neither teaches to consume sufficient liquid to hydrate the consumed fiber.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Dependent method claim 15 has been cancelled and rewritten as new dependent claim 41.

Claim 41 shows:

The method according to claim 37, further including admixing at least one ingredient selected from the group consisting of carbohydrates, fats, proteins, antioxidants, electrolytes, vitamins,

minerals, enzymes, coenzymes, plant derived compounds, synthetic orally absorbable nontoxic compounds, organoleptic agents, coloring agents, preservatives, flavoring agents, sweeteners, stimulants, and orally consumed substances that induce weight loss.

Claim 41 shows that numerous additional ingredients can be added to the base supplement. This provides a better description than claim 15 for the purposes of avoiding overlapping groups.

Instead of botanicals, herbs, and teas, applicant has provided the term “plant derived compounds” based on the original application. **All items added are not new matter and appear in original application.** Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant’s structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

DEPENDENT CLAIM 40 IS NEW

The method according to claim 37, further including admixing at least one edible fiber selected from the group consisting of soluble, partially soluble, and insoluble fibers.

Claim 40 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with Leitz’s 3 fiber groups , Gori’s bran groups, or the specific ratios of fiber weights proposed by Leitz, or the multiple brans taught by Gori.

Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences in number, type, and ratio of fibers needed, and the fact that applicant is a **minimum of 7 grams of fiber per serving** proves that applicant’s structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Applicant submits that although claim 13 was cancelled and rewritten as claim 37 it is similar to allowable claim 13 and provides further limitations as examiner suggested be placed in method claims. No new information has been added, all benefits listed are part of original application.

The dependent claims 14 and 15 were also allowable. They were cancelled and rewritten as claims 38-41 which more clearly define the method of administering applicant's novel physical structure.

Applicant submits the dependent claims are still allowable. Applicant submits they are allowable as they are similar to original allowable claims and contain further limitations examiner has suggested. Applicant submits the new dependent claims are also allowable as the independent claim 37 shows novel and unobvious subject matter over Leitz, making the dependent claims a fortiori patentable. Applicant believes the new dependent claims are also independently patentable over Leitz and Gori for the following reasons:

Claim 38 shows novel physical structure of applicant's invention with the limitation of providing an edible liquid to create a zero calorie or calorie beverage. This claim also includes the limitation of the beverage being at least 8 ounces.

Claim 39 shows novel physical structure of applicant's invention with the limitation of requiring at least one additional ingredient to make a solid or semi-solid. This claim further includes the limitation and step of requiring consumption of an edible liquid to further hydrate the consumed fiber.

Claim 40 shows novel physical structure of applicant's invention with the additional step of adding at least one additional fiber. Applicant does not teach a fiber ratio, and does not require a balance of fibers. Applicant further defines the additional fibers in a different manner than Leitz and Gori.

Claim 41 is similar to allowable cancelled claim 15 teaching that at least one additional ingredient can be admixed to further include additional elements that can be added to the method. The items have been selected to avoid overlapping groups. No information is new and all items are in original application.

Since independent claims 37 shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 38-41 are a fortiori patentable over Leitz and Gori.

THE NEW CLAIMS

Claims 42 and 45 , 48, 63, 64,

Independent method claim 16 was cancelled and rewritten as new independent claims 42 and 45. The office action stated that independent claim 16 was **rejected** under 35 U.S.C 103(a) as being unpatentable over the combination of Leitz (US patent 4,877,627) and Gori et. Al. (US Patent 4,784,961) . (This claim was considered obvious under Sec. 103 by the examiner). **This objection was cleared over the combination of Leitz and Gori under Sec 103 above.**

Applicant submits that claims 42 and 45 show novel physical structure and are unobvious over Leitz and Gori under Sec. 103.

INDEPENDENT METHOD CLAIMS 42 AND 45 SHOW NOVEL PHYSICAL STRUCTURE AND CLEAR LEITZ UNDER SECTION 102 (B)

Examiner did not object to claim 16 under Sec. 102. Because claim 16 was cancelled and rewritten as claims 42 and 45 applicant includes the following information for sake of completeness.

INDEPENDENT METHOD CLAIM 42 SHOWS NOVEL PHYSICAL STRUCTURE AND CLEAR LEITZ UNDER SEC. 102 (b)

Independent claim 42 shows a method of orally administering a nutritional supplement

containing at least seven grams of fiber per serving to a mammal comprising:

- (a) a mixture of guar, oat, and psyllium ,and
- (b) at least one flavoring agent, and

- (c) admixing at least one edible liquid selected from the group consisting of zero calorie and calorie containing liquids in sufficient quantity to create at least an 8 ounce beverage selected from the group consisting of zero calorie and calorie containing beverages, and
- (d) orally administering at least one serving of said beverage daily.

Applicant's novel physical structure includes a **minimum of 7 grams of fiber per serving, guar, oat, and psyllium**, at least one **flavoring agent**, the admixing of one edible liquid, the creation of an **8 ounce beverage**, the ability to make a beverage that is **zero calories**, the ability to make a **beverage that has calories**, and the **administration** of the fiber beverage **at least one time daily**. Applicant's invention is used for weight loss, cardiovascular risk reduction, and a variety of other health benefits.

LEITZ

Leitz is a balanced fiber composition that serves as an adjunct to the diet modeled after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non- vegetable, and non-cereal group. Leitz teaches that the novelty of his invention is the balance which provides benefits from fiber at a modest dose. This balance is made by using 9 different fibers in the specific ratios above. Leitz requires acerola, lemon and carrot pulp, corn, oat, and barley bran, guar, psyllium, and soy bran. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** This is why Leitz sets the maximum fiber per serving at 5 grams but prefers 1-3 grams for most forms of administration. Leitz prefers only 2 grams of fiber when his bulk powder is mixed in a liquid food product. Leitz further teaches inert non-toxic carriers, lubricants and binders are typically associated with his fiber composition. Finally, Leitz states that it is generally accepted

that soluble fiber is associated with a reduction in LDL and serum cholesterol. Leitz does not in any way show that his composition reduces cholesterol, nor does he provide any method of cholesterol lowering or cardiovascular risk reduction.

APPLICANT HAS MANY PHYSICAL STRUCTURAL DIFFERENCES OVER LEITZ

Applicant requires only 3 fibers not 9. Leitz just does not require 9 fibers, he requires very specific fibers and in very specific ratios. Leitz teaches the importance of his selected fibers for their benefit and for the fact that the balance is modeled after the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, fats, and proteins. He also teaches the importance of his fibers selected as they minimize the problems associated with fiber. Applicant does not set any ratios of the various fibers, Leitz sets very specific fiber ratios by dividing the fibers into 3 different fiber classifications. Applicant contains a minimum of 7 grams of fiber per serving. **Leitz teaches against high fiber** and sets the maximum fiber at 5 grams per serving, but prefers much less fiber per serving. Leitz can make a beverage, but it contains only 2 grams of fiber and **must be admixed with a liquid food product and an inert non toxic carrier to ease administration**. Applicant's novel physical structure allows for a beverage that does not require a liquid food product, or an inert non-toxic carrier and provides a minimum of 7 grams of fiber. Applicant adds the limitation of an **at least 8 ounce beverage**, which Leitz does not specify.

Applicant's novel physical structure is very different than Leitz and clears Leitz under Sec. 102

(b) Applicant's novel physical structure is unobvious and provides new and unexpected benefits and clears Leitz and Gori under Sec. 103 (a) as discussed above in amendment.

INDEPENDENT METHOD CLAIM 45 SHOWS NOVEL PHYSICAL STRUCTURE AND CLEARS LEITZ UNDER SEC. 102 (B)

Independent method claim 16 was cancelled and new independent method claim 45 was written to better show the novel physical structure. Examiner did not object to previous claim 16.

Applicant submits the following for new claim 45 for sake of completeness.

Claim 45 shows a method of orally administering a nutritional supplement containing at least seven grams of fiber per serving to a mammal comprising:

- (a) a mixture of guar, oat, and psyllium ,and
- (b) at least one flavoring agent, and
- (c) admixing at least one ingredient to said supplement to form an edible food product selected from the group of solid and semisolid food products consisting of puddings, snack bars, wafers, and dog bones
- (d) said edible food product to be accompanied by consumption of sufficient quantity of at least one edible liquid selected from the group of liquids consisting of zero calorie and calorie containing liquids to further hydrate the consumed fiber.

Leitz is described immediately above as part of claim 42 clearing Leitz under Sec. 102 (b).

APPLICANT'S NOVEL PHYSICAL STRUCTURE

Applicant's novel physical structure includes a **minimum of 7 grams of fiber per serving, guar, oat, and psyllium**, at least one **flavoring agent**, the admixing of at least one additional ingredient to make a semisolid or solid edible food product. These food products consist of snack bars, wafers, puddings and dog bones. Applicant notes in original application that semisolid and solid food products were discussed. Snack bars and puddings were discussed in detail. Applicant does not consider wafers and dog bones to be new matter as they were covered under the possibility of creating a semisolid or solid food product. Applicant's claim also includes the limitation of having to **administer the fiber supplement at least once daily and the limitation of requiring sufficient liquid to be consumed with the solid and semisolid food product to further hydrate the fiber**. Applicant's invention is used for weight loss, cardiovascular risk reduction, and a variety of other health benefits.

APPLICANT HAS MANY PHYSICAL STRUCTURAL DIFFERENCES OVER LEITZ

Applicant requires only 3 fibers not 9. Leitz just does not require 9 fibers, he requires very specific fibers and in very specific ratios. Leitz teaches the importance of his selected fibers for their benefit and for the fact that the balance is modeled after the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, fats, and proteins. He also teaches the importance of his fibers selected as they minimize the problems associated with fiber. Applicant does not set any ratios of the various fibers, Leitz sets very specific fiber ratios by dividing the fibers into 3 different fiber classifications. Applicant contains a minimum of 7 grams of fiber per serving. **Leitz teaches against high fiber** and sets the maximum fiber at 5 grams per serving, but prefers much less fiber per serving. Leitz prefers 1-3 grams of fiber per serving. Leitz describes a tablet (swallow), chew tablet, bulk powder for drink, bulk powder for granules to sprinkle on food. . **Applicant's novel physical structure allows for a pudding, snack bar, wafer and dog bone, none of which are taught by Leitz.** Applicant does not require an inert carrier, binder, or lubricant as Leitz does. Applicant provides a minimum of 7 grams of fiber per serving. **Leitz can have a maximum of 5 grams of fiber per serving but prefers 1-3 grams.** Applicant adds the limitation of an requiring **at least one additional liquid in sufficient quantity to further hydrate the fiber.** **Leitz recommends a liquid to wash down the chew tablet, not a sufficient quantity to hydrate the fiber!**

Applicant's novel physical structure is very different than Leitz and clears Leitz under Sec. 102 (b) Applicant's novel physical structure is unobvious and provides new and unexpected benefits and clears Leitz and Gori under Sec. 103 (a) as discussed above in amendment.

INDEPENDENT METHOD CLAIM 48 SHOWS NOVEL PHYSICAL STRUCTURE AND CLEARS LEITZ AND GORI UNDER SECTION 102 (b)

New independent method claim 48 has been written to show that the novel physical structure of applicant's invention provides a safe, easy way to lose weight. Claim 48 shows novel physical structure over Leitz and Gori.

A method of inducing weight loss in a mammal by orally administering a nutritional supplement containing at least seven grams of fiber per serving to a mammal comprising:

- (a) a mixture of guar, oat, and psyllium, and
- (b) at least one flavoring agent, and
- (c) administering said nutritional supplement at least one time daily.

Applicant's novel physical structure includes a **minimum of 7 grams of fiber per serving, guar, oat, and psyllium**, at least one **flavoring agent**. Claim 48 also includes the limitation of administering the supplement to a mammal and having to **administer the fiber supplement at least once daily**. Claim 48 shows that applicant's invention is used for weight loss.

LEITZ

Leitz is a balanced fiber composition that serves as an adjunct to the diet modeled after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non- vegetable, and non-cereal group. Leitz teaches that the novelty of his invention is the balance which provides benefits from fiber at a modest dose. This balance is made by using 9 different fibers in the specific ratios above. Leitz requires acerola, lemon and carrot pulp, corn, oat, and barley bran, guar, psyllium, and soy bran. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with**

fiber. This is why Leitz sets the maximum fiber per serving at 5 grams but prefers 1-3 grams for most forms of administration. Leitz prefers only 2 grams of fiber when his bulk powder is mixed in a liquid food product. Leitz further teaches inert non-toxic carriers, lubricants and binders are typically associated with his fiber composition. Leitz does not teach weight loss, nor does he provide a method of weight loss.

GORI

Gori teaches weight control not weight loss. He requires his invention to be taken with a proper diet that is with reduced fats, sugars and calories. Applicant respectfully submits that Gori does nothing and the weight control comes from the reduced fats, sugars, and calories. Applicant submits that Gori may cause weight gain as he requires 1 packet 10 times per day sprinkled on foodstuffs. This could create an increase in carbohydrates and calories and ultimately give weight gain.

Gori's weight control formulation **contains all** the significant dietary fiber components that should be present in a well-balanced natural diet. The substance of the invention is a scientifically balanced formulation of **essential natural fibers supplemented with the major minerals** that the use of such fibers requires. Gori's invention is designed to **restore the natural fiber that modern food technology is known to remove** from the processed foods which are consumed. Unlike other known products the Gori's invention is designed to **provide all fiber varieties known to generate specific health effects** deriving from regular fiber intake. He teaches **fibers are not to be considered equal to one another.** Gori's invention is a "food additive" that must be sprinkled on each meal of the day—suggested use is up to 10 packets per day for an average 150 lb individual and proportionally more or less based on body weight. Gori teaches to make a dry powder that is **sprinkled** on food and **contains 0.5-5 grams of fiber and mineral** supplements. Gori further teaches his invention with examples of **2.0 -3.3 grams per serving.** **Gori's invention must be sprinkled on foodstuff prior to ingesting it.**

GORI further teaches:

The fiber containing materials must contain **oat, corn and wheat bran along with at least one substance that is lubricative in the human bowels**. Gori teaches that the bran fibers are different and that the wheat is necessary as it supplies lignin, and corn is necessary as it supplies hemi-cellulose to the formulation. Gori teaches oat bran does not supply sufficient lignin or pectin to be employed by itself in the formulation, wheat bran is essential.

The formulation contains the **major minerals supplements** that use of essential natural fibers requires.

APPLICANT HAS MANY PHYSICAL STRUCTURAL DIFFERENCES OVER LEITZ AND GORI

Leitz does not teach weight loss or weight control. Leitz requires 9 fibers (applicant only 3), very specific fibers and in very specific ratios. Leitz teaches the importance of his selected fibers for their benefit and for the fact that the balance is modeled after the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, fats, and proteins. He also teaches the importance of his fibers selected as they minimize the problems associated with fiber. Applicant does not set any ratios of the various fibers, Leitz sets very specific fiber ratios by dividing the fibers into 3 different fiber classifications. Applicant contains a minimum of 7 grams of fiber per serving. **Leitz teaches against high fiber** and sets the maximum fiber at 5 grams per serving, but prefers much less fiber per serving. Leitz can make a beverage, but it contains only 2 grams of fiber and **must be admixed with a liquid food product and an inert non toxic carrier to ease administration**. Applicant's novel physical structure allows for a beverage that does not require a liquid food product, or an inert non-toxic carrier and provides a minimum of 7 grams of fiber. Applicant adds the limitation of an **at least 8 ounce beverage**, which Leitz does not specify.

Gori requires 7 fibers, very specific fibers and very specific minerals. Gori teaches to make a maximum of 5 grams of fiber per serving but actually prefers 1-3 grams. Gori requires oat, corn, and wheat bran. Applicant requires only oat bran and only requires 3 fibers. Gori is a food

additive sprinkled on foodstuffs throughout the day. Applicant is preferably a beverage (especially a zero calorie beverage), semisolid or solid that is not taught to be sprinkled on foodstuffs throughout the day. Applicant is a 7 gram minimum of fiber per serving. Applicant produces new and unexpected results including dramatic weight loss by creating satiety prior to the meal. Gori cannot promote weight control without the individual maintaining a diet with reduced fats, sugars, and calories.

Applicant's novel physical structure is very different than Leitz and Gori and clears Leitz and Gori both individually and in combination under Sec. 102 (b)

**INDEPENDENT METHOD CLAIM 48 SHOWS NOVEL
PHYSICAL STRUCTURE AND IS UNOBVIOUS OVER LEITZ
AND GORI AND CLEARS THE COMBINATION OF LEITZ
AND GORI UNDER SECTION 103 (a)**

Applicant's novel physical structure is unobvious and provides new and unexpected benefits and clears Leitz and Gori under Sec. 103 (a) as discussed above in amendment.

**LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR
COMBINATION, MUCH LESS THE MANNER PROPOSED**

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless

something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself....*Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound

scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual "to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered**

differently. Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

“That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.”.

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P. 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra , a “factual basis to support his conclusion that it would have been obvious” to make the combination.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES ARE INDIVIDUALLY COMPLETE

Applicant submits that Leitz and Gori should not be combined because each reference represents a complete and functional patent. Therefore, there is no reason to add or substitute parts of a patent with another patent.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant’s novel physical structure is unobvious and clears Leitz and Gori under Sec. 103

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE DIFFERENT APPROACHES

Leitz and Gori both propose a balanced fiber supplement, but they both take different approaches. Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight

control formulation that **requires minerals**. They are used for different purposes, as Leitz does not teach weight loss and Gori teaches weight control. They use different approaches to arrive at a balanced formula. **Leitz requires 9 fibers** from each of three groups. **Leitz does not feel wheat bran is important and instead teaches barley bran. Leitz requires acerola, carrot, and lemon pulp. Gori teaches all fibers are different and cannot be interchanged. Gori requires 7 fibers and teaches the necessity of corn, oat, and wheat bran.** Leitz's invention is a balanced fiber composition that serves as an adjunct to the diet. Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non-vegetable, and non-cereal group. (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** Finally, Leitz teaches a variety of unit-of-use administration [servings] in a variety of forms but does not teach it is a food additive to be sprinkled on all foodstuffs throughout the day. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TEACH AWAY FROM THE SUGGESTED COMBINATION

Leitz and Gori are two independent patents that teach how to make their individual inventions. They use different approaches and have different main functions. Leitz teaches a balanced fiber formulation to provide a beneficial total dietary fiber balance **modeled after the basic food**

group approach. Gori teaches primarily a balanced fiber composition for weight control. They both use a variety of fibers but recommend different percentages of certain classes of fibers. Leitz recommends 30-48.5% fiber from fruit and vegetable group, whereas Gori only 15%. Gori stresses the importance of the cereal group requiring corn, oat and wheat bran, it makes up 55% of his formulation. Gori stresses the importance of **wheat** and makes it essential to his formulation. Leitz recommends corn, oat and **barley** and **does not recommend wheat. Leitz teaches that the fibers he picked were carefully selected to provide the desired nutritional benefit. Gori requires specific minerals, Leitz does not.** Leitz requires acerola, carrot and lemon pulp, none of which are taught by Gori. Gori must be sprinkled on foodstuffs throughout the day, this is not required by Leitz. Applicant respectfully submits that these are different patents that require different essential elements, and therefore, teach a difference of opinion. Applicant respectfully does not understand how the differences could be brought into combination. Applicant respectfully submits because they teach away from being combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES BECAUSE THEY ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and certain percentages to make their invention. They are different. Applicant does not understand how two mutually exclusive elements can be combined. Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat, Leitz teaches barley. Leitz does not require minerals, Gori requires specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises** 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group **consisting of** acerola, carrot, or lemon. Gori uses the word "consisting of" in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than**

15% (pectin and cutins) in all tables in detailed description and claims. Gori requires a powder to be sprinkled on foodstuffs throughout the day, Leitz does not. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their different requirements. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE MUTUALLY EXCLUSIVE PATHS

Leitz and Gori cannot legally be combined because they take mutually exclusive paths to reach different solutions to a problem, therefore by implication each teaches away from combining itself with the other. Both teach a fiber composition to provide a fiber balance to mammal. They however teach different requirements are necessary to provide this balanced fiber. Leitz models, his fiber composition after the dietary fiber found in the basic food group approach to nutrition, **Gori's substance of his invention is designed to restore the natural fibers that modern food technology is know to remove from the processed foods (column 3 lines 40-44). Gori teaches to use brans with other gut influencing substances to formulate a weight control substance.** Leitz teaches the balance of fiber based on 3 groups and a variety of fibers within each group. Gori's formulation must be added to all foodstuffs throughout the day. Leitz does not teach this. **While both Leitz and Gori attempt to provide balanced fiber to a mammal, they use different approaches and this results in different functions.** Leitz does not teach weight control, Gori does. Leitz and Gori should not be combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES HAVE CLAIMED FEATURES LACKING

Even if Leitz and Gori could be combined certain claims would not be met. For example,

Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Leitz teaches administration 1-4 times per day. Gori requires his invention to be sprinkled on food stuffs throughout the day. Gori requires wheat bran, Leitz teaches barley bran. Gori teaches all fibers are different and cannot be interchanged. Applicant submits that Leitz and Gori would not meet all their claims if combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED DUE TO THE MULTIPLICITY OF STEPS REQUIRED

The combination requires a series of requirements set forth in the detailed descriptions and claims that makes trying to combine the two very difficult and not obvious. One would have to add wheat to Leitz and still obey the proper cereal ratio. The only fruit that Gori allows is pectin and cutin, and this goes against Leitz carefully selected acerola, lemon, and carrot pulp that provides the fiber balance he teaches. The end result would have to be powder that is sprinkled on foodstuffs throughout the day as Gori teaches. **One would not know how to resolve the difference between the fruit and vegetable total fiber ratio that is mutually exclusive, Leitz being 30-48.5% of total fiber, and Gori being 15% or less. Leitz teaches 30-48.5% from the cereal group, Gori 55%.** Great difficulty exists in trying to obey all the requirements of both references with respect to ratios and the great variety of fibers both teach. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

EVEN IF LEITZ AND GORI WERE TO BE COMBINED IN THE MANNER PROPOSED, THE PROPOSED COMBINATION WOULD NOT SHOW ALL OF THE NOVEL FEATURES OF CLAIM 48

However, even if the combination of Leitz and Gori were legally justified, claim 48 would still have novel (and unobvious) physical features over the proposed combination. In other words,

applicant's invention, as defined by claim 48 comprises much more than merely using oat, guar and psyllium.

Applicant's invention uses specific fibers with specific physical characteristics and properties (mesh sizes, viscosities, fat and water absorption). Applicant's novel physical structure allows **7 or more grams of fiber per serving** to be easily and safely administered to a mammal.

Applicant's novel invention also can be admixed with a liquid to create a beverage that does not immediately gel. Combining the variety of fibers in Leitz and Gori would immediately gel—the expected result. Combining Leitz and Gori does not produce weight loss as **Leitz does not teach how weight loss could occur, and although Gori teaches weight control without causing satiety, his formula still requires reduction of fats, sugar and calories—a diet itself that can give weight loss.** Applicant's invention produces dramatic weight loss in major part due to the satiety that it causes before the meal and for several hours afterward. Gori teaches weight control by the use of 3 different brans that modulate food moving in and out of the stomach. Gori requires at least one substance which is lubricative of the human bowels. Applicant teaches weight loss by creating satiety with fiber before the meal, so that the mammal feels full at time of the meal, and eats less. This reduction in calories consumed results in easy weight loss that does not require food avoidance or exercise. **Creating satiety prior to mealtime or snack time is an unexpected result. Having satiety that lasts for several hours after consuming applicant's invention is a new and unexpected result. Being able to lose weight without food avoidance, dieting, or exercise is a new and unexpected result.**

THE NOVEL PHYSICAL FEATURE OF CLAIM 48 PRODUCES NEW AND UNEXPECTED RESULTS AND HENCE ARE UNOBVIOUS AND PATENTABLE OVER THESE REFERENCES UNDER § 103

Also applicant submits that the novel physical features of claim 48 are also unobvious and hence patentable under § 103 since they produce new and unexpected results over Leitz and Gori, or any combination thereof.

Applicant is a medical board certified internal medicine doctor who has noted unexpected results in his patients.

These new and unexpected results include:

1. dramatic weight loss without avoiding foods an individual craves
2. dramatic weight loss without skipping meals
3. the versatility for invention to be used to skip meals or to consume all meals
4. the versatility for the invention to prevent or limit snacking
5. the versatility to make a zero calorie beverage as a snack or meal
6. The versatility to make a zero calorie beverage that will prevent calorie consumption at a meal
7. The versatility to make a zero calorie beverage that will prevent caloric consumption at a snack
8. Safe and healthy weight loss
9. Easy and sustained weight loss in individuals who have failed all other diets.
10. Healthy weight loss without the use of dangerous stimulants.

UNEXPECTED RESULTS

Applicant's invention produces superior weight loss results to other weight loss methods.

A) individuals who could not previously lose weight have lost weight

Individuals consuming applicant's invention have remarked that "This is the first time I am able to lose weight", "I have never been able to lose weight before", and "This is the easiest way to lose weight". Applicant is a physician who has documented weight loss in his office to confirm these statements.

B) Many individuals have lost more than 30 -50lbs and achieve their ideal body weight.

Applicant, a physician, has this documented in his medical office.

C) Individuals lose weight without avoiding foods they like. Most diets require food restriction.

Applicant's invention produces strong satiety prior to the meal so that fewer calories are

consumed during a meal, and weight loss occurs. It is unexpected that you can lose weight without dieting.

D) Individuals lose weight without exercising. Applicant's invention cuts calorie consumption enough that exercising is not a requirement to lose weight. Nearly all diets require increased activity to lose weight. It is an unexpected result that you can lose dramatic weight without exercise and without dangerous stimulants.

E) More unexpected results are discussed below (i.e., cardiovascular risk reduction benefits)

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PRODUCES UNEXPECTED RESULTS

Applicant's invention has novel physical structure comprising an ultra-high fiber (at least 7 grams per serving) supplement using 3 specific fibers with specific physical characteristics, and at least one flavoring agent that can be used to make a supplement containing at least 7 grams of fiber per serving and can be easily administered to a mammal as a liquid, semisolid or solid. Applicant, a board certified internal medicine doctor and expert in advanced lipid treatment, has noted several unexpected results amongst patients and users of his fiber supplement.

1. Safe, fast, easy weight loss occurs even in individuals who claim they have failed all diets. It is unexpected to see weight loss in individuals who claimed to have failed all other diets. Applicant has witnessed steady weight loss in his patients, and has received numerous comments regarding successful weight loss in individuals who stated they failed all other diets. Applicant's extremely high reorder rate is further proof of successful weight loss. Applicant's invention is safer because it does not contain dangerous stimulants. Applicant's invention works better than other weight loss formulas as foods do not need to be avoided, and exercise is not necessary to promote weight loss. Applicant is better than other diets in that it is totally customizable to the eating problem. Some individuals gain weight from snacking, others from overeating at meals.

Applicant's supplement can be customized to an individual's own eating problem.

Leitz's balanced fiber composition is a diet adjunct, not a weight reduction formula.

Leitz talks about the benefits of using higher dose fiber aiding in weight reduction but teaches it is not without risks and that is why he serves a "modest" not a high level of fiber (column 1 lines 56-67). Leitz offers no method, means or proof his invention will even lead to weight loss. **Gori is a weight control formula that must be taken by**

sprinkling on meals 10 times per day. Gori's weight control formula must be combined with dieting in reducing fats, sugars, and calories (column 4 lines 10-12).

Applicant respectfully submits, one does not know whether Gori's formula gives weight loss or the weight loss is due to dieting and reduction of calories. Furthermore, Gori makes a requirement of sprinkling on foodstuffs 10 times per day. This means calories are consumed 10 times per day and may potentially result in increased consumption of calories and weight gain!. **Applicant's invention produces new and unexpected results over the combination of Leitz and Gori with safe, easy, and many times dramatic weight loss.**

2. Applicant's weight loss occurs without need for food restriction and exercise. All diets not using orally consumed stimulants combine food restriction, avoidance, and exercise as an essential to losing weight. Applicant's novel physical structure promotes satiety that is long lasting and curbs appetite so that less food is consumed despite eating the individual's normal selections of food. Applicant believes novel physical structure allows weight loss to occur by other mechanisms described in specification as well. Applicant's invention works much better than other weight loss products because the need for will power to restrict certain foods is unnecessary, and the individual does not have to exercise. **Leitz teaches his composition is an adjunct to the diet that provides balanced fiber, he does not teach weight loss will occur. Gori is a weight control formula that does not teach weight loss can occur without adopting a proper diet and reducing fats, sugars, and calories.** (column 4 lines 10-13) **Applicant's invention**

produces new and unexpected results over the combination of Leitz and Gori with weight loss that occurs without having to avoid foods, and without exercising.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO OMISSION OF AN ELEMENT(S)

Leitz does not teach weight loss, Gori teaches weight control through the use of a variety of bran fibers and a lubricant fiber. Gori teaches that corn, wheat and oat are necessary to modulate the flow of food in and out of the stomach. Gori also requires very specific minerals. Leitz requires 9 specific fibers and Gori 7 fibers. Both have specific ratios of very specific fibers. Applicant is much simpler than Leitz and Gori as applicant requires only 3 fibers and does not require the plurality of brans that Gori teaches. Applicant does not require any fibers to be from the fruit and vegetable group. Applicant does not require any minerals. Leitz and Gori both teach a balance of fibers and teach away from high fiber, never recommending more than 5 grams per serving and in reality recommending only 1-3 grams per serving. Applicant requires no balance of fibers, no variety of fibers past the guar, oat, and psyllium, no minerals, and provides at least 7grams of fiber per serving, whereas the references never exceed 5 grams per serving.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to omission of several elements. .

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO UNSUGGESTED MODIFICATION

Leitz and Gori lack any suggestion that they should be modified to make applicant obvious. Leitz and Gori both teach a balanced fiber composition that requires a large variety of different fibers and both teach that the fiber per serving does not exceed 5 grams. Both prefer much lower

than 5 grams of fiber per serving. These references whether individual or in combination do not suggest making a fiber composition without a large variety of fiber, and they do not suggest using more than 5 grams of fiber. Applicant is an ultra-high fiber (at least 7 grams per serving) supplement that can be made with as few as 3 fibers, does not require minerals, nor specific fibers that the references teach.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unsuggested modification .

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LACK OF IMPLEMENTATION OF REFERENCES

If applicant's invention was obvious, surely someone would have made it by now. The fact that those skilled in the art have not made such an invention proves it is unobvious. Weight control is a multi-billion dollar business, surely if applicant's invention was obvious, someone would have already been making it.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to lack of implementation .

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO UNAPPRECIATED ADVANTAGE

Applicant's invention has many advantages that are tied to its ultra-high fiber (at least 7 grams per serving). The high dosage of fiber provides many unique benefits that do not result with smaller amounts of fiber per serving. Those skilled in the art have never appreciated the new and unexpected dramatic weight loss and other benefits that applicant provides.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unappreciated advantage.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
MISUNDERSTOOD REFERENCES**

Applicant respectfully feels that the references are misunderstood. Both references deal with a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. The addition of the minimum of 7 grams of fiber to the structure of the supplement should help clarify that applicant is a novel physical structure that is unobvious.

Leitz does not teach weight loss and Gori teaches weight control, yet his formula requires a diet with reduced fats, sugars, and calories indicating, his diet cannot achieve any weight control on its own. Applicant offers real weight loss that does not require a diet.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to misunderstood references.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO COMMERCIAL
SUCCESS**

Please refer to attached Declaration under rule 132 regarding commercial success.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO CONTRARIAN INVENTION

Leitz does not teach weight loss and Gori teaches weight control, yet his formula requires a diet with reduced fats, sugars, and calories, indicating his diet cannot achieve any weight control on its own. Applicant offers real weight loss that does not require a diet.

Leitz and Gori teach a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. Applicant teaches a weight loss formula that does not require a balanced fiber formulation, does not require specific fibers other than the guar, oat and psyllium, does not require minerals or inert carriers and applicant teaches an ultra-high fiber (at least 7 grams per serving) which is absolutely contrary to the references teaching of modest or small amounts of fiber per serving. Applicant is totally contrary to the references so cannot be obvious. Applicant respectfully does not understand how two references that teach totally different structure make applicant's novel physical structure obvious.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to contrarian invention.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LEITZ AND GORI BEING A PAPER PATENT

Applicant respectfully believes Leitz and Gori are not commercially available and are paper patents. These patents are over 10 years old and surely if they were viable, they would be selling commercially right now. Applicant is a medical doctor and expert in nutrition who is unaware of

these inventions being commercially sold. The fact they are not being sold despite the time advantage they have enjoyed indicates they should be construed very narrowly.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to the references being paper patents.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO APPLICANT'S NEW PRINCIPLE OF OPERATION

Applicant utilizes a new principle of operation. Applicant uses an ultra-high fiber (at least 7 grams per serving) composition when Leitz and Gori and others are recommending modest or small doses of fiber. Applicant has developed a method of using this high fiber to promote weight loss and a great variety of benefits. Applicant provides safe weight loss without yo-yo dieting and without the need for mineral and nutrient supplementation.

Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) beverage that does not immediately gel. Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) beverage that contains ZERO calories. Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) pudding, snack bar, wafer and dog bone. None of these have been provided by the references or prior art. Applicant has blazed several new trails so it must have been unobvious.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to several new principles of operation.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO APPLICANT SOLVING A DIFFERENT PROBLEM.

Leitz does not teach weight loss and Gori teaches weight control, yet his formula requires a diet with reduced fats, sugars, and calories indicating his diet cannot achieve any weight control on it's own. Applicant offers real weight loss that does not require a diet. Applicant solves a different problem than Leitz, as Leitz does not teach weight loss. Applicant solves a different problem than Gori. Gori teaches weight control that requires a variety of bran fibers, and a human bowel lubricant to supposedly promote weight loss by regulating the food moving in and out of the stomach. Gori requires a diet that is reduced in fats, sugar and calories.

Applicant teaches weight loss that does not require any diet, and certainly one does not have to reduce fats, sugar and calories. Applicant teaches successful weight loss by creating satiety prior to the meal , so a mammal eats less, and loses weight. Applicant solves the problem of will power that is not necessary with applicant's novel invention. By solving a different problem applicant's invention has to be unobvious.

Applicant has also solved the problem no other prior art has in creating an ultra-high fiber (at least 7 grams per serving) beverage that is Zero calories and also solved the problem of preventing immediate gelling.

Applicant has solved a variety of different problems than the references and the prior art and therefore, must be unobvious.

Applicant's novel physical structure is unobvious over the combination of Leitz and Gori under Sec. 103 due to applicant solving several different problems than references.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBTAINABLE OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LACK OF CONVINCING REASONING

Applicant respectfully does not understand how Leitz and Gori could be combined, and even if combined make applicant obvious. Applicant's novel physical structure is absolute opposite of what the two references teach. The references all have a different purpose as well. Leitz and Gori are more than 10 years old and are not being sold commercially. If these references' advantages were real, they likely would be sold today. Applicant does not understand the reasoning how two references that teach the opposite of what applicant teaches, could be combined and suddenly make applicant's novel structure obvious. Applicant does not see anything obvious in his physical structure or method claims when comparing to Leitz and Gori.

Applicant's novel physical structure is unobtainable over the combination of Leitz and Gori under Sec. 103 due to lack of convincing reasoning.

INDEPENDENT METHOD CLAIM 63 SHOWS A NEW USE METHOD CLAIM THAT HAS NOVEL PHYSICAL STRUCTURE AND CLEAR LEITZ AND GORI UNDER SECTION 102 (b)

Independent method claim 63 shows a new use method of reducing the risk of cardiovascular disease in mammals through reducing cardiac inflammation comprising orally ingesting an effective amount of fiber to lower high sensitivity C-reactive protein levels.

Cardiac inflammation greatly increases risk to a mammal of cardiovascular disease. This risk can be measured by high sensitivity C-reactive protein levels in mammals. The higher the levels of high sensitivity C-reactive protein the higher the risk of cardiovascular disease. This risk has good correlation with heart disease and is independent of the mammal's serum cholesterol.

When cardiac inflammation has been identified measures to reduce it must take place if risk

reduction is to occur. Current therapies for reducing high sensitivity C-reactive protein levels in humans include taking aspirin, quitting smoking, taking statin drugs, exercising and losing weight.

Applicant has discovered that numerous individuals consuming his invention have lowered their high sensitivity C-reactive protein levels and some very dramatically. Individuals with the highest levels of cardiac inflammation have dramatically reduced these levels down to the lowest most protective levels. Applicant provides support for this in the supplemental Declaration under Rule 132. Applicant has discovered that taking a sufficient amount of fiber can be very effective at reducing cardiac inflammation, and that the fiber can work by two methods. Cardiac inflammation and high sensitivity C-reactive protein levels can be reduced through using a fiber supplement that induces weight loss. Fat cells make interleukin which then travels to the liver to make c-reactive protein which then travels to the heart. By reducing the fat cells, one reduces the stimulation on the liver to make C-reactive protein. The other method of reducing cardiac inflammation and high sensitivity C-reactive protein comes from taking a sufficient amount of fiber per day without weight loss. A sufficient amount of fiber regardless of whether weight loss occurs or not, seems to lower high sensitivity C-reactive protein levels and cardiac inflammation. Applicant, a board certified internal medicine doctor, discovered this while actively treating patients who also consumed his novel invention.

Leitz and Gori do not teach anything about cardiac inflammation or high sensitivity C-reactive protein levels. Applicant is unaware of any prior art that reflect this.

Independent Method claim 63 shows novel physical structure and clear Leitz and Gori, the combination of the two, and prior art under section 102 (b)

**INDEPENDENT METHOD CLAIM 63 SHOWS NEW USE
METHOD CLAIM NOVEL PHYSICAL STRUCTURE AND IS
UNOBVIOUS OVER LEITZ AND GORI AND CLEARS THE**

COMBINATION OF LEITZ AND GORI UNDER SECTION 103

(a)

LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR COMBINATION, MUCH LESS THE MANNER PROPOSED

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199(CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself....*Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*” (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

“In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that ‘would lead’ that individual ‘to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant’s invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done.”

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1 column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He

provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently.** Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

“That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.”.

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P. 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra , a “factual basis to support his conclusion that it would have been obvious” to make the combination.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES ARE INDIVIDUALLY COMPLETE

Applicant submits that Leitz and Gori should not be combined because each reference represents a complete and functional patent. Therefore, there is no reason to add or substitute parts of a patent with another patent.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs

throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant's novel physical structure is unobvious and clears Leitz and Gori under Sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE DIFFERENT APPROACHES

Leitz and Gori both propose a balanced fiber supplement, but they both take different approaches. Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that **requires minerals**. They are used for different purposes, as Leitz does not teach weight loss and Gori teaches weight control. They use different approaches to arrive at a balanced formula. **Leitz requires 9 fibers** from each of three groups. **Leitz does not feel wheat bran is important and instead teaches barley bran. Leitz requires acerola, carrot, and lemon pulp. Gori teaches all fibers are different and cannot be interchanged. Gori requires 7 fibers and teaches the necessity of corn, oat, and wheat bran.** Leitz's invention is a balanced fiber composition that serves as an adjunct to the diet. Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non-vegetable, and non-cereal group. (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his**

balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber. Finally, Leitz teaches a variety of unit-of-use administration [servings] in a variety of forms but does not teach it is a food additive to be sprinkled on all foodstuffs throughout the day. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TEACH AWAY FROM THE SUGGESTED COMBINATION

Leitz and Gori are two independent patents that teach how to make their individual inventions. They use different approaches and have different main functions. Leitz teaches a balanced fiber formulation to provide a beneficial total dietary fiber balance **modeled after the basic food group approach.** Gori teaches primarily a balanced fiber composition for weight control. They both use a variety of fibers but recommend different percentages of certain classes of fibers. Leitz recommends 30-48.5% fiber from fruit and vegetable group, whereas Gori only 15%. Gori stresses the importance of the cereal group requiring corn, oat and wheat bran, it makes up 55% of his formulation. Gori stresses the importance of **wheat** and makes it essential to his formulation. Leitz recommends corn, oat and **barley** and **does not recommend wheat.** **Leitz teaches that the fibers he picked were carefully selected to provide the desired nutritional benefit. Gori requires specific minerals, Leitz does not.** Leitz requires acerola, carrot and lemon pulp, none of which are taught by Gori. Gori must be sprinkled on foodstuffs throughout the day, this is not required by Leitz. Applicant respectfully submits that these are different patents that require different essential elements, and therefore, teach a difference of opinion. Applicant respectfully does not understand how the differences could be brought into combination. Applicant respectfully submits because they teach away from being combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES BECAUSE THEY ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and certain percentages to make their invention. They are different. Applicant does not understand how two mutually exclusive elements can be combined. Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat, Leitz teaches barley. Leitz does not require minerals, Gori requires specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises** 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group **consisting of** acerola, carrot, or lemon. Gori uses the word “consisting of” in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims.** Gori requires a powder to be sprinkled on foodstuffs throughout the day, Leitz does not. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their different requirements. Applicant’s novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE MUTUALLY EXCLUSIVE PATHS

Leitz and Gori cannot legally be combined because they take mutually exclusive paths to reach different solutions to a problem, therefore by implication each teaches away from combining itself with the other. Both teach a fiber composition to provide a fiber balance to mammal. They however teach different requirements are necessary to provide this balanced fiber. Leitz models his fiber composition after the dietary fiber found in the basic food group approach to nutrition, **Gori’s substance of his invention is designed to restore the natural fibers that modern food technology is know to remove from the processed foods (column 3 lines 40-44).** Gori teaches to use brans with other gut influencing substances to formulate a weight control substance.

Leitz teaches the balance of fiber based on 3 groups and a variety of fibers within each group. Gori's formulation must be added to all foodstuffs throughout the day. Leitz does not teach this. **While both Leitz and Gori attempt to provide balanced fiber to a mammal, they use different approaches and this results in different functions.** Leitz does not teach weight control, Gori does. Leitz and Gori should not be combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES HAVE CLAIMED FEATURES LACKING

Even if Leitz and Gori could be combined certain claims would not be met. For example, **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Leitz teaches administration 1-4 times per day. Gori requires his invention to be sprinkled on food stuffs throughout the day. Gori requires wheat bran, Leitz teaches barley bran. Gori teaches all fibers are different and cannot be interchanged.** Applicant submits that Leitz and Gori would not meet all their claims if combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED DUE TO THE MULTIPLICITY OF STEPS REQUIRED

The combination requires a series of requirements set forth in the detailed descriptions and claims that makes trying to combine the two very difficult and not obvious. One would have to add wheat to Leitz and still obey the proper cereal ratio. The only fruit that Gori allows is pectin and cutin, and this goes against Leitz carefully selected acerola, lemon, and carrot pulp that provides the fiber balance he teaches. The end result would have to be powder that is sprinkled on foodstuffs throughout the day as Gori teaches. **One would not know how to resolve the difference between the fruit and vegetable total fiber ratio that is mutually exclusive Leitz**

being 30-48.5% of total fiber, and Gori being 15% or less. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Great difficulty exists in trying to obey all the requirements of both references with respect to ratios and the great variety of fibers both teach. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

THE NOVEL PHYSICAL FEATURE OF CLAIM 63 PRODUCES NEW AND UNEXPECTED RESULTS AND HENCE ARE UNOBVIOUS AND PATENTABLE OVER THESE REFERENCES UNDER § 103

Applicant submits that the novel physical features of claim 63 are also unobvious and hence patentable under § 103 since it produces a new and unexpected result over Leitz and Gori, or any combination thereof, or any other prior art.

Applicant is a board certified internal medicine doctor who has discovered that a sufficient amount of fiber administered to a mammal at least once per day will result in lowering of high sensitivity C-reactive protein levels, cardiac inflammation and reduce the risk of cardiovascular disease.

UNEXPECTED RESULTS

Many benefits of fiber are known, but applicant has discovered a new use of fiber. Applicant, a board certified internal medicine physician and lipid expert, discovered that high sensitivity C-reactive protein levels can be lowered with applicant's high fiber supplement. Fiber can be used to lower high sensitivity C-reactive protein levels, cardiac inflammation and ultimately reduce the risk of cardiovascular disease. Applicant has discovered that the reduction in high sensitivity C-reactive protein levels can come **with or without weight loss**. This is an incredibly important find as the few options we have to lower high sensitivity C-reactive protein today are not fully effective in most people, can have considerable costs, are difficult to comply with and are not easily maintained.

APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PRODUCES UNEXPECTED RESULTS

Applicant's invention has novel physical structure comprising an ultra-high fiber (at least 7 grams per serving) supplement using 3 specific fibers with specific physical characteristics, and at least one flavoring agent that can be used to make a supplement containing at least 7 grams of fiber per serving and can be easily administered to a mammal as a liquid, semisolid or solid. Administering the novel supplement at least one time daily can result in marked improvement in high sensitivity C-reactive protein levels, reduction in cardiovascular disease and in cardiovascular risk reduction.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO OMISSION OF AN ELEMENT(S)

Applicant's novel physical structure with an ultra-high fiber (at least 7 grams per serving) composition does not require specific fibers such as acerola, lemon, and carrot pulp, corn, wheat, barley, and soy bran etc. Applicant does not require inert non toxic carriers, binders, and minerals.

Applicant's novel physical structure is unobvious over the combination of Leitz and Gori under Sec. 103 due to omission of an element(s).

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO UNSUGGESTED MODIFICATION

Leitz and Gori lack any suggestion that they should be modified to make applicant obvious.

Leitz and Gori both teach a balanced fiber composition that requires a large variety of different fibers and both teach that the fiber per serving does not exceed 5 grams. Both prefer much lower than 5 grams of fiber per serving. These references whether individual or in combination do not suggest making a fiber composition without a large variety of fiber, and they do not suggest using more than 5 grams of fiber. Applicant is an ultra-high fiber (at least 7 grams per serving) supplement that can be made with as few as 3 fibers, does not require minerals, nor specific fibers that the references teach.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unsuggested modification .

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
UNAPPRECIATED ADVANTAGE**

Applicant's invention has many advantages that are tied to it's ultra-high fiber (at least 7 grams per serving). The high dosage of fiber provides many unique benefits that do not result with smaller amounts of fiber per serving. Those skilled in the art have never appreciated the new and unexpected dramatic reduction in high sensitivity C-reactive protein levels and resulting reduction in cardiac inflammation.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unappreciated advantage.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
MISUNDERSTOOD REFERENCES**

Applicant respectfully feels that the references are misunderstood. Both references deal with a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. The addition of the minimum of 7 grams of fiber to the structure of the supplement should help clarify that applicant is a novel physical structure that is unobvious.

Leitz does not teach anything about high sensitivity C-reactive protein levels. Applicant offers real reduction in high sensitivity C-reactive protein levels and weight loss is not required. .

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to misunderstood references.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO COMMERCIAL
SUCCESS**

Please refer to attached Declaration Under Rule 132 regarding commercial success.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO CONTRARIAN
INVENTION**

Leitz does not teach weight loss and Gori teaches weight control, yet his formula requires a diet with reduced fats, sugars, and calories indicating his diet cannot achieve any weight control on its own. Applicant offers real weight loss that does not require a diet.

Leitz and Gori teach a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. Applicant teaches a weight loss formula that does not require a balanced fiber formulation, does not require specific fibers other than the guar, oat and psyllium, does not require minerals, or inert carriers and applicant teaches an ultra-high fiber (at least 7 grams per serving) which is absolutely contrary to the references teachings of modest or small amounts of fiber per serving. Applicant is totally contrary to the references so cannot be obvious. Applicant respectfully does not understand how two references that teach totally different structure make applicant's novel physical structure obvious.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to contrarian invention.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LEITZ AND GORI BEING A PAPER PATENT

Applicant respectfully believes Leitz and Gori are not commercially available and are paper patents. These patents are over 10 years old and surely if they were viable, they would be selling commercially right now. Applicant is a medical doctor and expert in nutrition who is unaware of these inventions being commercially sold. The fact they are not being sold despite the time advantage they have enjoyed indicates they should be construed very narrowly.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to the references being paper patents.

APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO APPLICANT'S NEW PRINCIPLE OF OPERATION

Applicant utilizes a new principle of operation. Applicant uses an ultra-high fiber (at least 7 grams per serving) composition when Leitz and Gori and others are recommending modest or small doses of fiber. Applicant has developed a method of using this high fiber to promote reductions in high sensitivity C-reactive protein levels in mammals. Reduction in high sensitivity C-reactive protein levels lowers cardiac inflammation and risk of heart disease.

Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) beverage that does not immediately gel. Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) beverage that contains ZERO calories. Applicant also provides a new principle of operation in providing an ultra-high fiber (at least 7 grams per serving) pudding, snack bar, wafer and dog bone. None of these have been provided by the references or prior art. Applicant has blazed several new trails so it must have been unobvious.

Applicant's novel physical structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to several new principles of operation.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE IS UNOBVIOUS OVER THE
COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO APPLICANT
SOLVING A DIFFERENT PROBLEM**

Leitz and Gori do not teach anything about high sensitivity C-reactive protein levels. This is a different problem. High sensitivity C-reactive protein levels that are elevated represent increased inflammation in the heart and this leads to cardiovascular disease and plaque rupture. Applicant teaches this is an independent risk factor for heart disease and can be treated with an ultra-high fiber (at least 7 grams per serving) supplement that is administered once or more daily.

Applicant's physical structure is novel and unobvious and clears Leitz and Gori under Sec.103

(a)

INDEPENDENT MEANS CLAIM 64 SHOWS NOVEL PHYSICAL STRUCTURE AND FUNCTION AND CLEARS LEITZ AND GORI UNDER SECTION 102 (B)

Independent means claim 64 shows a nutritional supplement for oral administration to a mammal comprising:

A nutritional composition comprising a mixture of guar, oat, and psyllium, at least one flavoring agent, at least 7 grams of fiber per serving, and at least one edible liquid to create at least an 8 ounce beverage, and

an orally administered liquid means of delivering a minimum of 7 grams of fiber per serving that can be consumed in beverage form that does not immediately gel.

Means claim 64 shows the novel structure and the novel function of applicant's invention.

Applicant's novel physical structure includes a **minimum of 7 grams of fiber per serving, guar, oat, and psyllium**, at least one **flavoring agent**. Claim 64 also includes the limitation of administering the supplement to a mammal, **adding at least one edible liquid**, creating **at least an 8 ounce beverage**, and having to **administer the fiber supplement at least once daily**. Claim 64 shows that applicant's novel structure allows for a means of creating an ultra-high fiber (at least 7 grams per serving) beverage that does not immediately gel.

LEITZ

Leitz is a balanced fiber composition that serves as an adjunct to the diet modeled after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. Leitz teaches the balance is based

on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other described as non-fruit non- vegetable, and non-cereal group. Leitz teaches that the novelty of his invention is the balance which provides benefits from fiber at a modest dose. This balance is made by using 9 different fibers in the specific ratios above. Leitz requires acerola, lemon and carrot pulp, corn, oat, and barley bran, guar, psyllium, and soy bran. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** This is why Leitz sets the maximum fiber per serving at 5 grams but prefers 1-3 grams for most forms of administration. **Leitz prefers only 2 grams of fiber when his bulk powder is mixed in a liquid food product.** Leitz further teaches inert **non-toxic carriers, lubricants and binders are typically associated with his fiber composition.** Leitz does not teach weight loss, nor does he provide a method of weight loss.

GORI

Gori teaches weight control not weight loss. He requires his invention to be taken with a proper diet that is with reduced fats, sugars and calories. Applicant respectfully submits that Gori does nothing and the weight control comes from the reduced fats, sugars, and calories. Applicant submits that Gori may cause weight gain as he requires 1 packet 10 times per day sprinkled on foodstuffs. This could create an increase in carbohydrates and calories and ultimately give weight gain.

Gori's weight control formulation **contains all** the significant dietary fiber components that should be present in a well-balanced natural diet. The substance of the invention is a scientifically balanced formulation of **essential natural fibers supplemented with the major minerals** that the use of such fibers requires. Gori's invention is designed to **restore the natural fiber that modern food technology is known to remove** from the processed foods which are consumed. Unlike other known products the Gori's invention is designed to **provide**

all fiber varieties known to generate specific health effects deriving from regular fiber intake. He teaches **fibers are not to be considered equal to one another**. Gori's invention is a "food additive" that must be sprinkled on each meal of the day—suggested use is up to 10 packets per day for an average 150 lb individual and proportionally more or less based on body weight. Gori teaches to make a dry powder that is **sprinkled** on food and **contains 0.5-5 grams of fiber and mineral** supplements. Gori further teaches his invention with examples of **2.0 -3.3 grams per serving**. **Gori's invention must be sprinkled on foodstuff prior to ingesting it.**

Gori further teaches:

The fiber containing materials must contain **oat, corn and wheat bran along with at least one substance that is lubricative in the human bowels**. Gori teaches that the bran fibers are different and that the wheat is necessary as it supplies lignin, and corn is necessary as it supplies hemi-cellulose to the formulation. Gori teaches oat bran does not supply sufficient lignin or pectin to be employed by itself in the formulation, wheat bran is essential.

The formulation contains the **major minerals supplements** that use of essential natural fibers requires.

APPLICANT HAS MANY PHYSICAL STRUCTURAL DIFFERENCES OVER LEITZ AND GORI

Leitz requires 9 fibers (applicant only 3), very specific fibers and in very specific ratios. Leitz teaches the importance of his selected fibers for their benefit and for the fact that the balance is modeled after the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, fats, and proteins. He also teaches the importance of his fibers selected as they minimize the problems associated with fiber. Applicant does not set any ratios of the various fibers, Leitz sets very specific fiber ratios by dividing the fibers into 3 different fiber classifications. Applicant contains a minimum of 7 grams of fiber per serving. **Leitz teaches against high fiber** and sets the maximum fiber at 5 grams per serving, but prefers much less fiber per serving. Leitz can make a beverage, but it contains only 2 grams of fiber and must

be admixed with a liquid food product and an inert non toxic carrier to ease administration. Applicant's novel physical structure allows for a beverage that does not require a liquid food product, or an inert non-toxic carrier and provides a **minimum of 7 grams of fiber.** Applicant adds the limitation of an **at least 8 ounce beverage**, which Leitz does not specify.

Gori does not teach a liquid beverage, only a food additive that has to be sprinkled on all foodstuffs throughout the day. Gori requires 7 fibers, very specific fibers and very specific minerals. Gori teaches to make a maximum of 5 grams of fiber per serving but actually prefers 1-3 grams. Gori requires oat, corn, and wheat bran. Applicant requires only oat bran and only requires 3 fibers. Gori is a food additive sprinkled on foodstuffs throughout the day. Applicant is preferably a beverage (especially a zero calorie beverage), semisolid or solid that is not taught to be sprinkled on foodstuffs throughout the day. Applicant is a 7 gram minimum of fiber per serving. Applicant produces new and unexpected results including dramatic weight loss by creating satiety prior to the meal. Gori cannot promote weight control without the individual maintaining a diet with reduced fats, sugars, and calories.

Those versed in the prior art are well aware of the problems with mixing fibers. Fibers tend to gel quickly and this is exacerbated by the quantity of fibers and the increased percentage in solution. This is the reason why Leitz teaches a maximum of 5 grams of fiber per serving yet decreases it to 2 grams for a beverage. This is also why Leitz mentions the need for an inert carrier, to try to help prevent gelling. Leitz contains 9 fibers and can only make a 2 gram per serving solution, and it requires a liquid food product to ease administration. Applicant uses as few as 3 fibers and requires no carriers to make a minimum of 7 grams of fiber per serving beverage.

Applicant's novel physical structure is very different than Leitz and Gori and clears Leitz and Gori both individually and in combination under Sec. 102 (b)

**INDEPENDENT MEANS CLAIM 64 SHOWS NOVEL PHYSICAL
STRUCTURE AND FUNCTION AND IS UNOBVIOUS OVER LEITZ
AND GORI AND CLEARS THE COMBINATION OF LEITZ AND
GORI UNDER SECTION 103 (a)**

**LEITZ AND GORI DO NOT CONTAIN JUSTIFICATION TO SUPPORT THEIR
COMBINATION, MUCH LESS THE MANNER PROPOSED**

-With regard to the proposed combination of Leitz and Gori, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art § 103 rejection, *the references of themselves* (or some other prior art) must suggest that they be combined. E.G., as was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199 (CAFC 1983):

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO].”

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), “[w]here prior-art references require selective combination by the court to render obvious

a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself....*Something in the prior art must suggest the desirability and thus the obviousness of making the combination.*" (Emphasis supplied.)

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention, ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

In the present case, there is no reason given in the first O.A. to support the proposed combination. Leitz teaches to make a balanced fiber composition using 9 different fibers (table 1

column 3) that approximates the fiber in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats (Column 4 lines 30-35) that provides health benefits at a modest fiber dose which he proposes in 0.5-5 grams but more preferably 1-3 grams per serving. Gori teaches to make a fiber powder that is sprinkled on food and that contains essential minerals. He provides individual doses of 0.5-5grams but realistically refers to 1 gram packets given 10 times per day for an average 150 lb individual (column 4 lines 64-68). He states "Unlike other known products the substance of the invention is designed to prove all fiber varieties known to generate specific health effects from deriving from regular fiber intake." (Column3 lines 22-25). One cannot take two similar patents both dealing with trying to make a balanced fiber combination using multiple fibers (one containing 9, the other containing 7 varieties of fiber), using different fibers, using different ratios of fibers and mix them together and result in applicant's invention which is totally different. **Leitz and Gori teach fiber balance, specific types of fiber, specific ratios and the need for minerals, to make a formula that does not exceed 5 grams per serving. Applicant's novel structure includes 3 fibers, no specific fiber ratios, and results in an ultra-high fiber (at least 7 grams per serving) supplement that is administered differently.** Furthermore Gori teaches weight control, not dramatic weight loss. Gori teaches weight control that requires his fiber to be sprinkled on food. Applicant's invention teaches dramatic weight loss, and does not require consumption of food, and causes weight loss through creating satiety before the meal. Gori never mentions satiety because he focuses his invention on the belief that his invention controls weight through his sprinkled fibers adjusting the rate food enters and leaves the stomach. In regard to the fact that fiber detoxifies substance and binds to heavy metals and toxins in the stomach this is not taught by either Leitz or Gori, in fact Gori's fiber invention includes minerals including zinc, copper, and iron can bind to other minerals or vitamins taken by humans (i.e., iron binds to vitamin E and zinc). Gori does not even provide proof that the minerals combined with his fiber can be absorbed by a human. One would question how mineral replacement can occur when the mineral is given at the same time as the fiber.

The O.A. noted (p. 8) that the combination of Leitz and Gori produces advantages (broadens performance). Applicant submits that the fact that the combination produces advantages militates in favor of applicant because it proves that the combination produces new and unexpected results and hence is unobvious.

As stated in the above Levengood case,

“That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.”.

Applicant therefore submits that combining Leitz and Gori is not legally justified and is therefore improper. Thus they submit that the rejection on these references is also improper and should be withdrawn.

Applicant respectfully requests, if the claims are again rejected upon any combination of References, that the Examiner include an explanation, in accordance with M.P.E.P. 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra, a “factual basis to support his conclusion that it would have been obvious” to make the combination.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES ARE INDIVIDUALLY COMPLETE

Applicant submits that Leitz and Gori should not be combined because each reference represents a complete and functional patent. Therefore, there is no reason to add or substitute parts of a patent with another patent.

Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that includes minerals. Both teach different fibers to make their balanced formula. Gori is sprinkled on all foodstuffs throughout the day, Leitz does not recommend sprinkling on all foodstuffs throughout the day. These are separate stand alone inventions that teach a balance of fibers but teach balance very differently and require different fibers and different ratios of fibers and there is no reason to combine them.

Applicant's novel physical structure is unobvious and clears Leitz and Gori under Sec. 103

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE DIFFERENT APPROACHES

Leitz and Gori both propose a balanced fiber supplement, but they both take different approaches. Leitz is a balanced fiber composition modeled after the basic food groups and provides benefits of fiber based on a modest level of fiber. Gori is a balanced fiber weight control formulation that **requires minerals**. They are used for different purposes, as Leitz does not teach weight loss and Gori teaches weight control. They use different approaches to arrive at a balanced formula. **Leitz requires 9 fibers** from each of three groups. **Leitz does not feel wheat bran is important and instead teaches barley bran. Leitz requires acerola, carrot, and lemon pulp. Gori teaches all fibers are different and cannot be interchanged. Gori requires 7 fibers and teaches the necessity of corn, oat, and wheat bran.** Leitz's invention is a balanced fiber composition that serves as an adjunct to the diet. Leitz teaches the need to provide a beneficial total dietary fiber balance. (column 2 lines 43-45). He models the composition after the basic food group model and approximates the fiber composition found in a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. (column 4 lines 30-37). Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal group, and 3-40% from other

described as non-fruit non- vegetable, and non-cereal group. (column 2 lines 62-68) Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches that all of these fibers are needed as different fiber components were selected to obtain a balanced fiber composition. (column 3 lines 40-46) **Leitz teaches that large amounts of dietary fiber are dangerous and that his balanced composition provides modest levels of fiber intake that minimizes problems associated with fiber.** Finally, Leitz teaches a variety of unit-of-use administration [servings] in a variety of forms but does not teach it is a food additive to be sprinkled on all foodstuffs throughout the day. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TEACH AWAY FROM THE SUGGESTED COMBINATION

Leitz and Gori are two independent patents that teach how to make their individual inventions. They use different approaches and have different main functions. Leitz teaches a balanced fiber formulation to provide a beneficial total dietary fiber balance **modeled after the basic food group approach.** Gori teaches primarily a balanced fiber composition for weight control. They both use a variety of fibers but recommend different percentages of certain classes of fibers. Leitz recommends 30-48.5% fiber from fruit and vegetable group, whereas Gori only 15%. Gori stresses the importance of the cereal group requiring corn, oat and wheat bran, it makes up 55% of his formulation. Gori stresses the importance of **wheat** and makes it essential to his formulation. Leitz recommends corn, oat and **barley** and **does not recommend wheat.** **Leitz teaches that the fibers he picked were carefully selected to provide the desired nutritional benefit. Gori requires specific minerals, Leitz does not.** Leitz requires acerola, carrot and lemon pulp, none of which are taught by Gori. Gori must be sprinkled on foodstuffs throughout the day, this is not required by Leitz. Applicant respectfully submits that these are different patents that require different essential elements, and therefore, teach a difference of opinion. Applicant respectfully does not understand how the differences could be brought into

combination. Applicant respectfully submits because they teach away from being combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES BECAUSE THEY ARE IMPOSSIBLE TO COMBINE

Leitz and Gori are impossible to combine. As discussed above, each carefully picked certain fibers and certain percentages to make their invention. They are different. Applicant does not understand how two mutually exclusive elements can be combined. Leitz teaches 30-48.5% of total fiber from the fruit and vegetable group, Gori 15%. Leitz teaches 30-48.5% from the cereal group, Gori 55%. Leitz requires acerola, carrot, and lemon, Gori does not. Gori requires wheat, Leitz teaches barley. Leitz does not require minerals, Gori requires specific minerals. Very importantly, the wording in the claims shows the two references cannot be combined. Leitz **comprises** 30-48.5% fiber from the fruit and vegetable group and must contain at least one of the group **consisting of** acerola, carrot, or lemon. Gori uses the word "consisting of" in his main claim and thus closes the formulation to new elements. **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims.** Gori requires a powder to be sprinkled on foodstuffs throughout the day, Leitz does not. Applicant submits that those skilled in the art would find it impossible to combine these two references with all their different requirements. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES TAKE MUTUALLY EXCLUSIVE PATHS

Leitz and Gori cannot legally be combined because they take mutually exclusive paths to reach different solutions to a problem, therefore by implication each teaches away from combining itself with the other. Both teach a fiber composition to provide a fiber balance to mammal. They

however teach different requirements are necessary to provide this balanced fiber. Leitz models, his fiber composition after the dietary fiber found in the basic food group approach to nutrition, **Gori's substance of his invention is designed to restore the natural fibers that modern food technology is know to remove from the processed foods (column 3 lines 40-44). Gori teaches to use brans with other gut influencing substances to formulate a weight control substance.** Leitz teaches the balance of fiber based on 3 groups and a variety of fibers within each group. Gori's formulation must be added to all foodstuffs throughout the day. Leitz does not teach this. **While both Leitz and Gori attempt to provide balanced fiber to a mammal, they use different approaches and this results in different functions.** Leitz does not teach weight control, Gori does. Leitz and Gori should not be combined Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED AS REFERENCES HAVE CLAIMED FEATURES LACKING

Even if Leitz and Gori could be combined certain claims would not be met. For example, **Leitz demands that the fiber from the fruit and vegetable group be 30-48.5% of the total fiber, Gori never teaches more than 15% (pectin and cutins) in all tables in detailed description and claims. Leitz teaches administration 1-4 times per day. Gori requires his invention to be sprinkled on food stuffs throughout the day. Gori requires wheat bran, Leitz teaches barley bran. Gori teaches all fibers are different and cannot be interchanged.** Applicant submits that Leitz and Gori would not meet all their claims if combined. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

LEITZ AND GORI SHOULD NOT BE COMBINED DUE TO THE MULTIPLICITY OF STEPS REQUIRED

The combination requires a series of requirements set forth in the detailed descriptions and claims that makes trying to combine the two very difficult and not obvious. One would have to add wheat to Leitz and still obey the proper cereal ratio. The only fruit that Gori allows is pectin and cutin, and this goes against Leitz carefully selected acerola, lemon, and carrot pulp that provides the fiber balance he teaches. The end result would have to be powder that is sprinkled on foodstuffs throughout the day as Gori teaches. **One would not know how to resolve the difference between the fruit and vegetable total fiber ratio that is mutually exclusive, Leitz being 30-48.5% of total fiber, and Gori being 15% or less. Leitz teaches 30-48.5% from the cereal group, Gori 55%.** Great difficulty exists in trying to obey all the requirements of both references with respect to ratios and the great variety of fibers both teach. Applicant's novel physical structure is unobvious over Leitz and Gori under sec. 103.

THE NOVEL PHYSICAL FEATURE OF CLAIM 63 PRODUCES NEW AND UNEXPECTED RESULTS AND HENCE ARE UNOBVIOUS AND PATENTABLE OVER THESE REFERENCES UNDER § 103

Applicant submits that the novel physical features of claim 63 are also unobvious and hence patentable under § 103 since it produces a new and unexpected result over Leitz and Gori, or any combination thereof, or any other prior art.

Applicant is a board certified internal medicine doctor who has discovered that applicant's novel physical structure can create an ultra-high fiber (at least 7 grams per serving) beverage that does not immediately gel. This provides many advantages, and provides a safe and easy manner to consume large quantities of fiber. Gori does not teach a beverage and Leitz teaches a beverage that contains only 2 grams of fiber per serving, and requires inert non-toxic carriers and a liquid food product to ease administration. Applicant does not require any carriers, or liquid food products, and contains a minimum of 7 grams of fiber per serving.

Applicant's novel physical structure is unobvious over Leitz and Gori and clears Leitz and Gori under section 103 (a) .

APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO OMISSION OF AN ELEMENT(S)

Applicant's novel physical structure with an ultra-high fiber (at least 7 grams per serving) composition does not require specific fibers such as acerola, lemon, and carrot pulp, corn, wheat, barley, and soy bran etc. Applicant does not require inert non toxic carriers, binders, and minerals. Applicant omits all these elements and makes a beverage that contains at least 7 grams of fiber per serving and does not immediately gel. Gori does not teach a beverage, Leitz teaches a beverage that contains only 2 grams of fiber per serving and requires a liquid food product and inert carriers to ease administration.

Applicant's novel physical structure and function is unobvious over the combination of Leitz and Gori under Sec. 103 due to omission of an element(s).

APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO UNSUGGESTED MODIFICATION

Leitz and Gori lack any suggestion that they should be modified to make applicant obvious. Leitz and Gori both teach a balanced fiber composition that requires a large variety of different fibers and both teach that the fiber per serving does not exceed 5 grams. Both prefer much lower than 5 grams of fiber per serving. These references whether individual or in combination do not suggest making a fiber composition without a large variety of fiber, and they do not suggest using more than 5 grams of fiber. Applicant is an ultra-high fiber (at least 7 grams per serving) supplement that can be made with as few as 3 fibers, does not require minerals, nor specific

fibers that the references teach. Leitz teaches against high fiber and only recommends a beverage containing 2 grams of fiber .

Applicant's novel physical structure and function is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unsuggested modification .

Applicant's novel physical structure and function is unobvious over the combination of Leitz and Gori under Sec. 103 due to lack of implementation of references.

Applicant's invention has novel physical structure and allows invention to deliver an ultra-high fiber (at least 7 grams per serving) supplement to a mammal in a safe and easy manner.

Applicant's novel structure allows for beverage to be created that does not immediately gel.

Gori does not teach a beverage. Leitz teaches a beverage that is only 2 grams of fiber and requires a liquid food product and an inert carrier. Applicant's novel structure allows for a minimum of 7 grams of fiber to be administered by simply admixing and edible liquid. If applicant's invention was obvious, surely someone skilled in the art would have made it by now. The fact that those skilled in the art did not make it, despite its great advantages proves it is unobvious.

Applicant's novel physical structure is unobvious over Leitz and Gori and clears both individually and in combination under Sec. 103.

APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO UNAPPRECIATED ADVANTAGE

Applicant's invention has many advantages that are tied to its ultra-high fiber (at least 7 grams per serving) and the ease of which it can be administered as a liquid beverage that is easy to consume and does not immediately gel. The high dosage of fiber provides many unique benefits that do not result with smaller amounts of fiber per serving. Those skilled in the art have never

appreciated the new and unexpected dramatic health benefits such as dramatic weight loss and dramatic reduction in the risk of cardiovascular disease that could be accomplished with applicant's novel structure delivered in a beverage containing at least 7 grams of fiber.

Applicant's novel physical structure and function is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to unappreciated advantage.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS
OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
MISUNDERSTOOD REFERENCES**

Applicant respectfully feels that the references are misunderstood. Both references deal with a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. The addition of the minimum of 7 grams of fiber to the structure of the supplement should help clarify that applicant is a novel physical structure that is unobvious.

Gori does not teach a beverage. Leitz teaches only a 2 gram fiber per serving beverage that requires inert carriers. Applicant has novel physical structure that permits novel function whereby at least 7 grams of fiber can be admixed with a liquid to create a beverage that does not immediately gel.

Applicant's novel physical structure and function is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to misunderstood references.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS
OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
COMMERCIAL SUCCESS**

Please see refer to attached Declaration Under Rule 132 regarding commercial success.

**APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS
OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO
CONTRARIAN INVENTION**

Gori does not teach a beverage. Leitz does not teach a beverage that contains more than 2 grams of fiber per serving. Leitz requires 9 different fibers, Gori 7. Leitz requires an inert non toxic carrier and Gori requires minerals. Applicant only requires 3 fibers and can make a minimum of 7 gram fiber per serving beverage that does not immediately gel. Leitz and Gori teach fiber balance requiring a large variety of different fibers, and against high levels of fiber per serving and that is why both teach a maximum of 5 grams per serving, and prefer much less. Gori spaces his 10 grams of fiber over the entire day with 10 separate packets to keep the fiber per serving low.

Leitz does not teach weight loss and Gori teaches weight control, yet his formula requires a diet with reduced fats, sugars, and calories indicating his diet cannot achieve any weight control on it's own. Applicant offers real weight loss that does not require a diet.

Leitz and Gori teach a balanced fiber composition requiring a large variety of specific fibers, minerals, specific ratios and both teach against high fiber. Applicant is 180 degrees opposite the references both individually and in combination. Applicant teaches a weight loss formula that does not require a balanced fiber formulation, does not require specific fibers other than the guar, oat and psyllium, does not require minerals, or inert carriers and applicant teaches an ultra-high fiber (at least 7 grams per serving) which is absolutely contrary to the references teachings of modest or small amounts of fiber per serving. Applicant is totally contrary to the references so cannot be obvious. Applicant respectfully does not understand how two references that teach totally different structure make applicant's novel physical structure obvious.

Applicant's novel physical structure and function is unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to contrarian invention.

APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LEITZ AND GORI BEING A PAPER PATENT

Applicant respectfully believes Leitz and Gori are not commercially available and are paper patents. These patents are over 10 years old and surely if they were viable, they would be selling commercially right now. Applicant is a medical doctor and expert in nutrition who is unaware of these inventions being commercially sold. The fact they are not being sold despite the time advantage they have enjoyed indicates they should be construed very narrowly. Applicant is unaware of any fiber drink with applicant's novel physical structure and containing 7 grams of fiber per serving and applicant's invention is commercially available..

Applicant's novel physical structure and function is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to the references being paper patents.

Applicant's novel physical structure and function is unobvious over the combination of Leitz and Gori under Sec. 103 due to applicant's new principle of operation.

Applicant utilizes a new principle of operation. Applicant uses an ultra-high fiber (at least 7 grams per serving) composition when Leitz and Gori and others are recommending modest or small doses of fiber. Applicant has developed an ultra-high fiber (at least 7 grams per serving) supplement that can be admixed with an edible liquid to create a beverage that does not immediately gel. Applicant's novel structure can be admixed with water to create a zero calorie beverage that does not immediately gel.

Applicant teaches his novel structure does not require minerals or nutrient supplements, inert carriers, binders, or lubricants, all required by the quoted references. Applicant has blazed several new trails so it must have been unobvious.

Applicant's novel physical structure and function is novel and unobvious over Leitz and Gori and clears Leitz and Gori under Sec. 103 due to several new principles of operation.

APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO APPLICANT SOLVING A DIFFERENT PROBLEM

Leitz teaches a balanced fiber composition that is modeled after the basic food groups. Gori teaches a weight control formula that requires a variety of bran fibers and an intestinal lubricant combined with a diet with reduced fat, calories, and sugar.

Applicant teaches an ultra-high fiber (at least 7 grams per serving) supplement that can be used for a variety of health benefits and does not require minerals, inert non-toxic carriers, or 7-9 specific fibers, specific fiber ratios etc. Applicant can be used for weight loss without eating a diet low in fat, sugar and calories. Applicant solves a variety of different problems including dramatic risk reduction in cardiovascular disease, and cardiac inflammation. Applicant's novel physical structure solves the new problem of how to deliver ultra-high fiber (at least 7 grams per serving) to a mammal safely, and easily. Gori and Leitz teach modest fiber per serving.

Applicant's physical structure and function is novel and unobvious and clears Leitz and Gori under Sec. 103 (a)

**APPLICANT'S NOVEL PHYSICAL STRUCTURE AND FUNCTION IS UNOBVIOUS
OVER THE COMBINATION OF LEITZ AND GORI UNDER SEC. 103 DUE TO LACK
OF CONVINCING REASONING**

Applicant has novel physical structure and function. Leitz and Gori teach away from applicant's structure. Applicant provides many new and unexpected results. Applicant is opposite prior arts teachings of necessity of replacing nutrients and minerals with high fiber intake. Applicant's novel physical structure allows for an edible liquid to be admixed and creation of a beverage that contains at least 7 grams of fiber

THE DEPENDENT CLAIMS ARE A FORTIORI PATENTABLE

Since independent claims 37, 42, 45, and 48 shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 38-41, 43-44, 46-47, and 49-52 are a fortiori patentable over Leitz and Gori

For examiner's clarification:

Dependent claim 14 has been cancelled and rewritten as new dependent claims 38, 39, 49, 50

Dependent claim 15 has been cancelled and rewritten as new claim 41

Dependent claim 17 has been cancelled and rewritten as new claims 44, 47, and 52

Dependent claim 3 was cancelled and rewritten as new Dependent claim 40

Dependent claim 3 was cancelled and rewritten as new Dependent claim 43

Dependent claim 3 was cancelled and rewritten as new Dependent claim 46

Dependent claim 3 was cancelled and rewritten as new Dependent claim 51

Moreover applicant submits that the following dependent claims 38-41, 43-44, 46-47, and 49-52 are independently patentable over Leitz for the following reasons.

Claims 38, and 49 are method claims that teach an edible liquid can be admixed to applicant's ultra-high fiber (at least 7 grams per serving) comprising guar, oat, psyllium, and flavoring agent to create a beverage. One novel feature is that a ZERO calorie beverage can be made. This claim also includes the limitation of needing sufficient quantity to create at least an 8 oz. beverage. Gori does not teach a beverage. Leitz teaches a beverage that is only 2 grams and requires a liquid food product. Leitz does not have an at least 8 ounce limitation. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claims 39 and 50 are method claims that teach that by admixing at least one ingredient to applicant's ultra-high fiber (at least 7 grams per serving) supplement comprising guar, oat, psyllium and a flavoring agent an edible semisolid or solid food product can be made. The edible food product can be a pudding, snack bar, wafer, or dog bone. This method claim also includes the limitation of the need to consume sufficient quantity of edible liquid to further hydrate the fiber. Gori teaches only a food additive that is sprinkled on meals. **Leitz teaches a tablet, chew tablet, bulk powder for beverage or granules and does not teach a pudding, snack bar, wafer, or dog bone. Leitz does not teach to further hydrate his fiber composition with sufficient liquid. Leitz does describe using a liquid to help swallow the chew tablet, it is not for hydration of the fiber.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claims 40, 43, 46, 51 teaches additional fibers that can be added and specifies them by their solubility. Leitz teaches fibers based on 3 groups, vegetable and fruit, cereal, and other. Leitz requires very specific ratios of each group. Applicant does not use these groups and instead uses soluble, partially soluble and insoluble. These provide different means of classifying the fibers. **Applicant does not require the ratios of fiber groups which are a necessity with Leitz.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving

proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Claims 41, 44, 47, 52 are method claims that show that additional ingredients can be added to applicant's ultra-high fiber (at least 7 grams per serving) supplement. These ingredients are all covered in original application. Gori teaches 7 very specific minerals are required and gives their weight per 100 grams. Applicant allows the addition of any mineral and no specific weight is given. Leitz does not teach the possibility of adding most of the ingredients applicant has included. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and clears Leitz under sections 102 and 103.

Since independent claim 16 was cancelled and rewritten as new claim 42 & 45 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claim 17 was cancelled and rewritten as new dependent claims 43-44, 46-47 and are a fortiori patentable over Leitz and Gori.

Since independent claim 18 was cancelled and rewritten as new claim 53 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 54-57 are a fortiori patentable over Leitz and Gori

Since independent claim 21 was cancelled and rewritten as new claim 58 that shows novel and unobvious subject matter over Leitz and Gori, the dependent claims 59-62 are a fortiori patentable over Leitz and Gori

Since independent claims 24, 42, 45, 53, and 58 are shown to recite novel and unobvious subject matter over Leitz, all the dependent claims 26-36, 43-44, 46-47, 54-57, and 59-62 listed above are a fortiori patentable over Leitz and Gori.

Moreover applicant submits that the following dependent claims 26-36, 43-44, 46-47, 54-57, and 59-62 are independently patentable over Leitz and Gori for the following reasons.

Claim 25 provides specific gram amounts for the guar, oat, and psyllium that are much greater in gram weight than Leitz and Gori. Leitz and Gori's **maximum** combined weight of guar, oat and psyllium is less than 1 gram, applicant's **minimum** combined weight of the same three fibers is 2.5 grams. This proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 26 shows admixing at least one ingredient allows for a liquid, semisolid or solid. Leitz teaches tablets, chew tablets, bulk powder, granules, and a 2 gram fiber beverage mixed with liquid food stuffs. Gori teaches only a powder that is sprinkled on food stuffs. Leitz and Gori show a maximum of 5 grams of fiber per serving but prefer 1-3 grams. Neither shows a semisolid administration form. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 27 teaches additional fibers that can be added and specifies them by their solubility. Leitz teaches fibers based on 3 groups, vegetable and fruit, cereal, and other. Gori teaches that a variety of bran fibers are necessary to control flow of food in and out of the stomach. Applicant does not use these groups and instead uses fibers based on solubility. These provide different means of classifying the fibers. Applicant does not require any further fibers, but additional fibers can be added. Applicant does not require the ratios of fiber groups which are a necessity with Leitz. These differences and the fact that applicant is a minimum of 7 grams of fiber per

serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 28 teaches how to make a beverage and a zero calorie beverage. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 29 teaches how to make a semisolid or solid especially a pudding, snack bar, wafer or dog bone. Leitz does not teach these comestibles, instead teaches a tablet, chew tablet, and granules. Gori teaches only powder to sprinkle on food stuffs. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103..

Claim 30 further defines the flavoring agents that are a necessary part of applicant's supplement. Leitz does not require a flavoring agent but could add one. Gori does not mention flavoring agents. Leitz is associated with a binder, inert carrier or lubricant, applicant is not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 31 teaches that additional ingredients that improve visual or organoleptic appeal can be added. Leitz does not discuss thickening agents, thinning agents, or emulsifiers. Leitz discusses need for a binder, lubricant, or inert carrier perhaps to hold the tablet together. Gori does not teach thickening agents, thinning agents, or emulsifiers. These differences, the differences

number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 32 teaches an antioxidant can be added. Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 33 teaches a tea can be added, Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 34 teaches vitamins, minerals, coenzymes, electrolytes etc. can be added, Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 35 teaches one caloric ingredient can be added including carbohydrates, fats, and proteins. Leitz and Gori do not. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 36 shows a preferred alternate embodiment with green tea, multianthocyanadins, folic acid, pyridoxine, locust bean gum, pectin, and at least one sweetener and flavoring agent. Leitz and Gori do not teach this structure, and instead teach a balanced structure with 7-9 fibers. . This

shows very different structure than Leitz and Gori. Leitz and Gori teach very specific fibers and locust bean gum is not one of them. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 43 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 44 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 46 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 47 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact

that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 54 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 55 shows that additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 56 teaches how to make a beverage and a **zero calorie beverage**. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 57 further describes the method of making a semisolid or solid comestible and the additional step of consuming a liquid to hydrate the fiber. Leitz and Gori do not teach a pudding, wafer, snack bar, or dog bone. Neither teaches to consume sufficient liquid to hydrate the consumed fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber

per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 59 shows that additional fibers can be added to base supplement. These fibers are grouped by solubility and have nothing to do with the 3 fiber groups proposed by Leitz, or the multiple brans taught by Gori. Applicant does not teach any ratios, on the contrary, Leitz and Gori do. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 60 shows that numerous additional ingredients can be added to the base supplement. Leitz and Gori do not teach the addition of these ingredients other than flavoring agents and specific minerals (Gori). These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori and clears Leitz and Gori under sections 102 and 103.

Claim 61 teaches how to make a beverage and a **zero calorie beverage**. Gori does not teach a beverage. Leitz teaches only a 2 gram beverage that is admixed with a liquid food product. Applicant has 7 grams of fiber per serving and can be admixed with water. Applicant requires at least one flavoring agent, making a liquid food product unnecessary. **Applicant puts in the limitation of a minimum of an 8 oz beverage which Leitz does not. Leitz does not teach a ZERO calorie beverage.** These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Claim 62 further describes the method of making a semisolid or solid comestible and the additional step of consuming a liquid to hydrate the fiber. Leitz and Gori do not teach a pudding, wafer, snack bar, or dog bone. **Neither teaches to consume sufficient liquid to hydrate the**

consumed fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Leitz and Gori clears Leitz and Gori under sections 102 and 103.

Therefore applicant submits that dependent claims 26-36,43-44, 46-47,54-57, and 59-62 are independently patentable over Leitz and Gori and should a fortiori be allowed.

NON- APPLIED REFERENCES

Ringe et al Patent 5,026,689 is a non-applied reference. Applicant has reviewed it and found that it is a totally different invention. Ringe is a **ready to eat cereal** that is high in psyllium. Ringe teaches a cereal containing 2%-37% psyllium, **20-80% starchy cereal component**, and about **5-15% insoluble fiber**. Ringe teaches a method to make a **cereal** and its use for cholesterol lowering. Ringe reports blood serum cholesterol reductions of 5%-20%. Applicant, a physician and expert in lipid management, points out that this is **not LDL reduction**. Total serum cholesterol is an unreliable yardstick to follow as day to day variations can fluctuate widely. Ringe teaches how to make several examples of his ready-to-eat cereal, all of them requiring multiple ingredients (nearly 20 in every example). Applicant's novel physical structure is both novel comprising a nutritional supplement containing a minimum of **7 grams of fiber per serving** and comprising **guar, oat, and psyllium and at least one flavoring agent**. **Applicant does not teach a cereal. Applicant does not teach the numerous ingredients Ringe uses to make the cereal. Applicant does not teach a limitation on moisture or fructose content, etc.** Applicant has novel physicals structure and is unobvious over Ringe and clears Ringe under Sec. 102 and 103.

Day et al. Patent 4,824,672 is a non-applied reference. Applicant has reviewed it and found that it is a totally different invention. Day is a pharmaceutical composition comprising a gel-forming fiber **and a mineral salt**. The mineral salt must be selected from the group consisting of calcium carbonate, magnesium carbonate, and potassium carbonate. It appears that Day

recommends only one gel forming fiber selected from a markush group and recommends only one mineral salt. Day specifies a **ratio range whereby the gel-forming fiber is 3:1 to 10:1** over the mineral salt. Day teaches this is a formulation for cholesterol lowering, not for weight loss, raising HDL, or lowering high sensitivity C-reactive protein levels. Day does not specify a gram dose of fiber per serving, instead he states “an effective amount of gel-forming fiber”. Day teaches a **5 gram guar and calcium carbonate** formulation in a 5:1 ratio that was served in a capsule **3 times** per day. (column 6 lines 5-15). Day administered his formulation **with each meal**. Day did not demonstrate HDL rise, or triglyceride lowering. Applicant’s novel physical structure is both novel comprising a nutritional supplement containing a minimum of **7 grams of fiber per serving** and comprising (**at least 3 fibers**) guar, oat, and psyllium and a flavoring agent. **Applicant does not require a mineral salt. Applicant does not require a ratio of a gel-forming fiber and a mineral salt. Applicant does not administer with each meal.** Applicant provides data showing more effective LDL lowering than Day. Applicant has novel physical structure and is unobvious over Day and clears Day under Sec. 102 and 103.

CONCLUSION

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. All claims recite novel and unobvious subject matter over Leitz. To review, Leitz teaches a balanced fiber composition that is to be used as an adjunct to the diet. The novelty of his invention is that he teaches a balanced fiber composition that allows him to serve a modest fiber dosage that provides benefits yet minimizes the problems associated with fiber. Fundamental to Leitz’s teachings is that **large doses of fiber are dangerous**. Key to his “balance” is the great variety of different fibers, each in a specified ratio. Leitz teaches 9 specific fibers are needed to provide the balance and include acerola, lemon and carrot pulp, corn, oat, barley, and soy bran, psyllium and guar. Leitz teaches these specific fibers are modeled after a balanced diet containing the recommended portions of carbohydrates, proteins, and fats. Leitz teaches the balance is based on providing 30-48% of fiber in the composition from fruit or vegetable sources, 30-48% of the fiber from the cereal

group, and 3-40% from other described as non-fruit non- vegetable, and non-cereal group. Leitz teaches that within each of the 3 groups 3 preferred fibers were selected and the preferred balance of each of these fibers was determined. Leitz teaches a serving dose of 0.5-5 grams of fiber (**maximum**) but prefers 1-3 grams for most embodiments and only 2 grams for a beverage. **Applicant submits that Leitz never intended to use more than 5 grams of fiber per serving, as he never recommends more than 3 grams per serving.** Leitz teaches that his composition typically contains non-toxic inert carriers, binders, lubricants, etc. to aid with oral administration. Finally, Leitz states that it is generally accepted that soluble fiber is associated with a reduction in LDL and serum cholesterol. Leitz does not in any way show that his composition reduces cholesterol, nor does he provide any method of cholesterol lowering. There is no evidence that Leitz composition contains the proper amounts of specific soluble fibers to lower cholesterol. There could also be negative consequences to the large number of fibers, the particular fibers themselves, or the interactions between the carriers, lubricants and binders. Leitz does not teach weight loss.

Gori teaches to make a weight control formulation. He teaches a balanced fiber formulation and defines balance differently. He specifically teaches his formulation provides **all** fiber varieties known to generate specific health benefits. He teaches that fibers are not to be considered equal to each other. Key to his teaching is that **corn, oat, and wheat bran are required, and at least one substance that is a bowel lubricant. Essential to his formulation is the necessity of including minerals. He teaches manganese, selenium, zinc, copper, iron, calcium and magnesium are necessary to replace the minerals that are kelated or sequestered by the fiber.** He teaches the **dangers of high fiber and a maximum of 5 grams of fiber per serving.** There is no intention to use more than 5 grams of fiber per serving as Gori only recommends 1-3.3 grams and this includes his mineral weight. Gori is really in his own words a “food additive” that needs to be sprinkled on food 10 times per day. Gori teaches his formula provides weight control and reduces blood cholesterol and triglicerides [misspelled]. Applicant respectfully questions the necessity and benefits of minerals added to fiber that he teaches sequesters or kelates minerals. **How can his formula replace minerals when those exact minerals are**

related and sequestered by his fibers? Applicant respectfully questions the legitimacy of Gori having anything to do with weight control, weight loss, or lipid improvement. **His invention requires a proper diet with reduced fats, sugars, and calories.** Applicant submits the “proper” diet he refers to is scientifically known to control weight and improve cholesterol. Why would one need his weight control formula if they follow a calorie reduced diet? Gori suggests cholesterol benefits but provides no proof or method. Applicant, a physician and lipid expert, respectfully submits there is no proof that Gori actually results in any cholesterol benefit for the same reasons listed under Leitz.

Applicant teaches a nutritional supplement that is an ultra-high fiber (at least 7 grams per serving) supplement comprising guar, oat, psyllium and a flavoring agent. Applicant is entirely different from Leitz, Gori, and the combination of the two. Applicant submits that Leitz and Gori cannot be combined. Assuming Leitz and Gori could be combined, applicant has provided numerous arguments above showing that applicant has novel structure and is unobvious over the combination of Leitz and Gori under Sec. 103. Applicant teaches dramatic health benefits including dramatic easy weight loss, and dramatic an unexpected benefits in LDL, HDL, triglycerides, lipoproteins, homocysteine and high sensitivity C-reactive protein levels. Applicant’s novel structure requires only 3 specific fibers—not 7-9 specific fibers. **Applicant does not require specific fiber ratios, balanced formulation, minerals, inert carriers, binders, or lubricants.** Applicant’s serving size of fiber is a **minimum of 7 grams**, Leitz and Gori are a **maximum of 5 grams** and prefer much less. Applicant’s novel structure allows a **minimum** of 7 or more grams of fiber to be safely and easily to a mammal without danger or need for nutrient supplement. Applicant prefers administration with a beverage, pudding, snack bar, wafer, or dog bone. **Gori teaches only a food additive sprinkled** on food 10 times per day. Leitz prefers a tablet, chew tablet, or bulk form that could be used to make a beverage or granules that can be sprinkled on food. Leitz beverage is very different than applicant’s. **Leitz recommends only 2 grams of fiber and must be admixed with a liquid food stuff and inert carrier to ease administration (and still needs 9 specific fibers in their specified ratios).** Applicant provides a minimum of 7 grams of fiber, and does not require a liquid food product or

inert carrier. Furthermore, applicant can be made into a zero calorie beverage. Applicant respectfully believes he has diligently responded to all issues in the office action. Therefore applicant submits that this application is now in condition for allowance, which applicant respectfully solicits.

CONDITIONAL REQUEST FOR CONSTRUCTIVE ASSISTANCE

Applicant has made diligent effort to amend the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason, the Examiner believes that the claims of this application are not yet in full condition for allowance, applicant respectfully requests his constructive assistance and suggestions pursuant to the spirit of MPEP Sec. 2173.02 and 707.07. This will enable the undersigned to place this application in fully allowable condition as soon as possible and without the need for further proceedings. Applicant authorizes the Examiner to make any needed minor corrections or changes.

Very respectfully,



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Enc:

Attachment

Declaration Under Rule 132 of Commercial Success A₁-A₄

Exhibits to Declaration Under Rule 132 ~~A₁-A₄~~ B₁-B₁₃ C₁-C₁₁ D₁-D₇ E₁-E₁₂
F₁-F₂₃ G₁-G₁₆

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I hereby certify that this correspondence, and attachments will be deposited with the United States Postal Service by First Class Mail, postage prepaid, in an envelope addressed to Commissioner of Patents, Washington DC 20231 on the date below.

Date: April 16, 2003

Inventor's Signature 